

January 2016

**Supporting Statement
Importation of Fresh Apple and Pear Fruit
into the Continental United States from
Certain Countries in the European Union
APHIS-2015-0073
OMB No. 0579-XXXX**

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), is responsible for preventing plant pests and noxious weeds from entering the United States, preventing the spread of plant diseases not widely distributed in the United States, and eradicating those imported pests and noxious weeds when eradication is feasible.

Under the Plant Protection Act (7 U.S.C. 7701 – et seq.), the Secretary of Agriculture is authorized to carry out operations or measures to detect, eradicate, suppress, control, prevent, or retard the spread of plant pests new to the United States or not known to be widely distributed throughout the United States.

The regulations in “Subpart – Fruits and Vegetables” (Title 7, Code of Federal Regulations (CFR) 319.56, referred to as the regulations), prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests that are new to or not widely distributed within the United States.

APHIS is proposing to amend the regulations to allow the importation of fresh apple and pear fruit from certain countries in the European Union into the continental United States, provided that the fruit is produced in accordance with a systems approach as an alternative to importation under the current preclearance program. The proposed systems approach for fresh apple and pear fruit consists of production site and packinghouse registration, inspection of registered production sites twice a season, production site pest control and sanitation, post-harvest safeguards, fruit culling, traceback, sampling, cold treatment against Mediterranean fruit fly in countries where the pest is known to occur, a phytosanitary certificate, port of entry inspection, and importation as commercial consignments only. Fresh apple and pear fruit that does not meet the requirements in the systems approach would continue to be allowed to be imported into the United States subject to the conditions of the preclearance program.

This action would provide an alternative for the importation of fresh apple and pear fruit from certain countries in the European Union while continuing to provide protection against the introduction of plant pests into the continental United States.

APHIS is asking Office of Management and Budget (OMB) to approve, for 3 years, its use of these information collection activities associated with its efforts to prevent the spread of plant pests and plant diseases into the United States.

2. Indicate how, by whom, and for what purpose the information is 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 verify that apple and pear fruit from the European Union are grown in production areas that are registered and monitored by the National Plant Protection Organization (NPPO) to verify consignments have been produced with a systems approach:

319.56.75(a)(1) Operational Workplan (foreign government) -The NPPO of the exporting country must provide an operational workplan to APHIS that details the activities that the NPPO would, subject to APHIS' approval of the workplan, carry out to meet the requirements of this section. Note: Cold treatment procedures and schedules would also be included in the Operational Workplan. Apple and pear fruit being exported from countries where Medfly is known to occur would be required to undergo cold treatment (319.56-75(d)).

319.56.75(b)(1) Production Site Registration (business) (foreign government) - Production sites where the fresh apple and pear fruit is grown must be registered with the NPPO of the exporting country.

319.56.75 (b)(2) Monitoring (foreign government) -The NPPO of the exporting country or officials authorized by the NPPO must monitor pest populations at production sites in order to determine the need and timing of such control measures and ensure effective control of pests. The NPPO must also ensure that registered production sites are inspected twice every season with emphasis on the quarantine pests listed in the operational workplan.

319.56.75 (c)(1) Packinghouse Registration (business) (foreign government) - All fresh apple and pear fruit for export to the continental United States must be packed in packinghouses that are registered and approved by the NPPO of the exporting country.

319.56.75 (c)(1) Packinghouse Tracking System (business) -Packinghouses must be able to exclude plant pests and have a tracking system to identify individual production sites in accordance with the operational workplan.

319.56.75 (c)(5) Box Markings with Site Identification (business) - Each shipping box must be marked with the identity of the packing facility, the production site, and grower or grower organization to ensure traceback.

319.56.75 (e) Phytosanitary Inspection (business) (foreign government) -After post-harvest processing, the NPPO of the exporting country or officials authorized by the NPPO of the exporting country must inspect the apple and pear fruit for signs of pest infestation and confirm absence of the pests listed in the operational workplan.

319.56.75 (e) Investigation of Suspended Sites and Remedial Action (foreign government) - The NPPO of the exporting country is required to reject the consignment and may suspend the production site and/or packing house from importation to the continental United States for the remainder of that season. If any of these pests are found in a consignment at U.S. ports of entry,

APHIS may reject the consignment and may suspend the production site and/or packing house until an investigation is completed by the NPPO of the exporting country and APHIS. The investigation may include site visits by APHIS and/or reports from the NPPO of the exporting country. Procedures for disqualification of production sites and/or packing houses will be detailed in the operational work plan. The exportation to the continental United States of fresh apple and pear fruit from the rejected production site may resume in the next growing season if an investigation is conducted and APHIS and the NPPO of the exporting country agree that appropriate remedial actions have been taken.

319.56.75 (f) Phytosanitary Certificate (foreign government) - Each consignment of fresh apple or pear fruit must be accompanied by a phytosanitary certificate issued by the NPPO of the exporting country certifying that the fruit meets the conditions under § 319.56-74 for export to the continental United States.

305.6(a) Certification of Treatment Facilities (business) - All facilities or locations used for refrigerating fruits or vegetables in accordance with the cold treatment schedules in the PPQ Treatment Manual or in another treatment schedule approved in accordance with §305.2 must be certified by APHIS. Recertification of the facility or carrier is required every 3 years, or as often as APHIS directs, depending on treatments performed, commodities handled, and operations conducted at the facility.

305.6(d)(6) Numbered Seal (business) - Only the same type of fruit in the same type of package may be treated together in a container; no mixture of fruits in containers may be treated. A numbered seal must be placed on the doors of the loaded container and may be removed only at the port of destination by an official authorized by APHIS.

305.6(d)(12) Review of Treatment Records (business) - Cold treatment is not completed until so declared by an official authorized by APHIS or the certifying official of the foreign country; consignments of treated commodities may not be discharged until APHIS clearance has been fully completed, including review and approval of treatment record charts.

305.6(d)(14) Audits (business) - An official authorized by APHIS may perform audits to ensure that the treatment procedures comply with the regulations in this section and that the treatment is administered in accordance with the treatment schedules in the PPQ Treatment Manual or in accordance with another approved treatment schedule. The official authorized by APHIS must be given the appropriate materials and access to the facility, container, or vessel necessary to perform the audits.

305.6(e) Cold Treatment Monitoring (business) - Treatment must be monitored by an inspector to ensure proper administration of the treatment. An inspector must also approve the recording devices and sensors used to monitor temperatures and conduct an operational check of the equipment before each use and ensure sensors are calibrated. An inspector may approve, adjust, or reject the treatment.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, 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.

APHIS has not control or influence over when foreign countries will automate phytosanitary certificates. However, APHIS is involved with the Government-wide utilization of the International Trade Data System (ITDS) via the Automated Commercial Environment (ACE) to improve business operations and further Agency missions. This will allow respondents to submit the data required by U.S. Customs and Border Protection and its Partner Government Agencies (PGAs), such as APHIS, to import and export cargo, such as many fruits, through a Single Window concept. APHIS is also establishing a system known as e-File for CARPOL (Certification, Accreditation, Registration, Permitting, and Other Licensing) activities. This new system will strive to automate some of these information collection activities. The system is still being developed and business processes continue to be identified and mapped.

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 APHIS collects is exclusive to its mission of preventing the entry of injurious plant pests, diseases, and noxious weeds and is not available from any other source.

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

APHIS estimates that 95 percent of the respondents are small entities.

6. Describe the consequences 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.

APHIS is the only Federal Agency responsible for preventing the incursion or interstate spread of plant pests, diseases, and noxious weeds. The information APHIS is collecting is the only source for the information and it is not being collected through other forms or reports. If this information is not collected, APHIS' ability to protect the United States from injurious plant pests, diseases, and noxious weeds would be severely compromised.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, governmental contract, grant-in-aid, or tax records for more than three years;
- in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

No 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.

In 2015, APHIS held productive consultations with the following individuals concerning the information collection activities associated with its program to import fresh apple and pear fruit from the European Union:

Ms. Dana Irina Simion
 Health & Consumer Protection Directorate
 General European Commission
 Rue de la Loi 200
 B-1049 Brussels Belgium
 Phone: 322-295-9182

Mr. Leonard Bosschaert , Counselor
 Federal Agency for the Safety of the Food Chain – DG Control Policy
 International Affairs CA
 Botanique Food Safety Center - Boulevard du Jardin Botanique 55
 B1000 Brussels Belgium
 Phone: 322-208-3884
 Dr. Jean Luc Angot, Deputy Director General, CVO

Head of the Sanitary Coordination Actions
Directorate General of Food – Ministry of Agriculture, Food and Fisheries
251 rue de Vaugirard,
75732 Paris Cedex 15, France
Email: jean-luc.angot@agriculture.gouv.fr

APHIS' proposed rule (Docket No. APHIS-2015-0073) will describe its information gathering requirements, and also provide a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

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

This information collection activity involves no payments (other than appropriate, program-related 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 and attitudes, religious beliefs, and others that are 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 asks 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 for hour burden estimates.

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

Respondents are foreign businesses and the NPPO in France, Belgium, Italy, Germany, Poland, The Netherlands, Spain, and Portugal. The annualized cost to respondents is 31,217.

APHIS arrived at this figure by multiplying the total burden hours (1,007) by the estimated average hourly wage of the above respondents (\$31) based on information provided by APHIS' International Service specialists and country attachés. (1,007 x \$31.00 = \$31,217)

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

There is zero annual cost burden associated with capital and start-up costs, maintenance costs, and purchase of services in connection with this program.

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

The estimated cost for the Federal Government is \$33,084 (see APHIS Form 79).

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

This is a new program for APHIS.

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

APHIS has no plans to tabulate or publish the information collected.

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.

There are no USDA forms in this information collection.

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

APHIS is able to certify compliance with all the provisions in the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in this information collection.