

August 2016

Supporting Statement
Importation of Fresh Mango Fruit from
Vietnam into the United States
Docket No. APHIS-2016-0026
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 mango fruit from Vietnam into the continental United States. As a condition of entry, fresh mango fruit from Vietnam would be subject to a systems approach that would include orchard requirements, irradiation treatment, and port of entry inspection. The fruit would also be required to be imported in commercial consignments and accompanied by a phytosanitary certificate issued by the National Plant Protection Organization of Vietnam with an additional declaration stating that the consignment was inspected and found free of Macrophoma mangiferae and Xanthomonas campestris pv. mangiferaeindicae.

This action would allow for the importation of fresh mango fruit from Vietnam while continuing to provide protection against the introduction of plant pests into the continental United States.

APHIS is asking the Office of Management and Budget (OMB) to approve 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 fresh mango fruit from Vietnam are grown in accordance with a systems approach monitored by the NPPO and to verify consignments are declared free of pests.

305.9(a)(1)(i) - Irradiation Facility Detailed Layout Plan (business) - Prospective facility operators must submit a detailed layout of the facility site and its location to APHIS. APHIS will evaluate plant health risks based on the proposed location and layout of the facility site. APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from port of entry or points of origin in the United States.

305.9(a)(1)(iv) - Facility Contingency Plan (business) -The facility must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles if the facility is unable to properly treat a shipment

305.9(a)(1)(vi) – Facility Treatment Arrangements (business) -Treatment arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility.

305.9(a)(1)(viii) – Facility Pest Management Plan and Map (business) -The facility must maintain and provide APHIS with an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility. Proximity of host material to the facility will necessitate trapping or other pest monitoring activities to help prevent establishment of any escaped pests of concern, as approved by APHIS; these activities will be listed in the compliance agreement required in paragraph (c)(1)(i) of this section. The treatment facility must have a pest management plan within the facility.

305.9(b) - Facility Approval and Written Concurrence (business) -The irradiation treatment facility must be approved by APHIS. Other agencies that have regulatory oversight and requirements must concur in writing with the establishment of the facility prior to APHIS approval. In order to be approved, a facility must fulfill the requirements in paragraphs (c) and (d) of this section.

305.9(c) and (c)(ii) - Compliance Agreement (foreign government) (business) - If irradiation of imported articles is conducted outside the United States, the operator of the irradiation facility must sign a compliance agreement with APHIS and the national plant protection organization (NPPO) of the country in which the facility is located. In this agreement, the facility operator must agree to comply with the requirements of this section, and the NPPO of the country in which the facility is located must agree to monitor that compliance and to inform the Administrator of any noncompliance.

305.9(d) - Facility Certification (business) -The irradiation treatment facility must be certified by APHIS. Recertification is required in the event of an increase in the amount of radioisotope, a decrease in the amount of radioisotope for a reason other than natural decay, a major modification to equipment that affects the delivered dose, or a change in the owner or managing entity of the facility. Recertification also may be required in cases where a significant variance in dose delivery has been measured by the dosimetry system.

305.9(e) - Monitoring and Interagency Agreements (business). Treatment must be monitored by an inspector. This monitoring will include inspection of treatment records and unannounced inspections of the facility by an inspector, and may include inspection of articles prior to or after irradiation.

305.9(e)(2) – Irradiation Facilities’ Operations Notifications (business) - Facilities in foreign countries that carry out irradiation operations must notify the Director of Preclearance, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1236, of scheduled operations at least 30 days before operations commence, except where otherwise provided in the facility preclearance workplan. To ensure the appropriate level of monitoring, before articles may be imported in accordance with this section, the following agreements must be signed, in addition to the irradiation treatment framework equivalency workplan required in paragraph (e)(1) of this section:

305.9(e)(2)(i) - Facility Preclearance Workplan (foreign government) - Prior to commencing importation into the United States of articles treated at a foreign irradiation facility, APHIS and the NPPO of the country from which articles are to be imported must jointly develop a preclearance workplan that details the activities that APHIS and the foreign NPPO will carry out in connection with each irradiation facility to verify the facility's compliance with the requirements of this section. Typical activities to be described in this workplan may include frequency of visits to the facility by APHIS and foreign plant protection inspectors, methods for reviewing facility records, and methods for verifying that facilities are in compliance with the requirements for separation of articles, packaging, labeling, and other requirements of this section. This facility preclearance workplan will be reviewed and renewed by APHIS and the foreign NPPO on an annual basis.

305.9(e)(2)(ii) - Trust Fund Agreement (foreign government) - Irradiated articles may be imported into the United States in accordance with this section only if the NPPO of the country in which the irradiation facility is located or a private export group has entered into a trust fund agreement with APHIS. That agreement requires the NPPO or the private export group to pay, in advance of each shipping season, all costs that APHIS estimates it will incur in providing inspection and treatment monitoring services at the irradiation facility during that shipping season. Those costs include administrative expenses and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by APHIS in performing these services. The agreement will describe the general nature and scope of APHIS services provided at irradiation facilities covered by the agreement, such as whether APHIS inspectors will monitor operations continuously or intermittently, and will generally describe the extent of inspections APHIS will perform on articles prior to and after irradiation. The agreement requires the NPPO or private export group to deposit a certified or cashier's check with APHIS for the amount of those costs, as estimated

by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement further requires the NPPO or the private export group to deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before any more articles irradiated in that country may be imported into the United States. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the NPPO or the private export group or held on account until needed, at the option of the NPPO or the private export group.

305.9(f)(2)(i)(A) – Packaging/Seals (business) - Articles that are irradiated in accordance with this section must be packaged in cartons in the following manner: In insect-proof cartons that have no openings that will allow the entry of the pests of concern. The cartons must be sealed with seals that will visually indicate if the cartons have been opened. The cartons may be constructed of any material that prevents entry or oviposition (if applicable) by the pests of concern into the articles in the carton

305.9(f)(2)(iii)(A) - Labeling (business) - Packaging must be labeled in a manner that allows an inspector to determine treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment. For imported articles that are treated prior to arrival in the United States, pallets that remain intact as one unit until entry into the United States may have one such label per pallet. Pallets that are broken apart into smaller units prior to or during entry into the United States, or that will be broken apart into smaller units after entry into the United States, must have the required label information on each individual carton.

305.9(k) - Recordkeeping (business) - An irradiation processor must maintain records of each treated lot for 1 year following the treatment date, and must make these records available for inspection by an inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except holidays). These records must include the lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

305.9(l) - Request for Facility Certification and Inspection of Facility (business) - Persons requesting initial certification of an irradiation treatment facility must submit the request for approval in writing to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Inspection and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606-5202. The initial request must identify the owner, location, and radiation source of the facility, and the applicant must supply additional information about the facility construction, treatment protocols, and operations upon request by APHIS if APHIS requires additional information to evaluate the request. Before the Administrator determines whether an irradiation facility is eligible for certification, an inspector will make a personal inspection of the facility to determine whether it complies with the standards of this section.

305.9(m) - Denial and Withdrawal of Certification Appeal (business) - The Administrator will withdraw the certification of any irradiation treatment facility upon written request from the irradiation processor. (2) The Administrator will deny or withdraw certification of an irradiation treatment facility when any provision of this section is not met. Before withdrawing or denying certification, the Administrator will inform the irradiation processor in writing of the reasons for the proposed action and provide the irradiation processor with an opportunity to respond. The

Administrator will give the irradiation processor an opportunity for a hearing regarding any dispute of a material fact, in accordance with rules of practice that will be adopted for the proceeding. However, the Administrator will suspend certification pending final determination in the proceeding if he or she determines that suspension is necessary to prevent the spread of any dangerous insect. The suspension will be effective upon oral or written notification, whichever is earlier, to the irradiation processor. In the event of oral notification, written confirmation will be given to the irradiation processor within 10 days of the oral notification. The suspension will continue in effect pending completion of the proceeding and any judicial review of the proceeding.

319.56-75(b)(2) – Orchard of Origin/Phytosanitary Inspections (foreign government) (business) - The orchard of origin be inspected at a time prior to the beginning of harvest and be found free of Macrophoma mangiferae

319.56-5(d) & 305.9(h) - Phytosanitary Certificates (foreign government) (business) - Each consignment of fresh mango fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Vietnam that contains an additional declaration stating that the fruit in the consignment was inspected and found free of Macrophoma mangiferae and Xanthomonas campestris pv. mangiferaeindicae and has been produced in accordance with the requirements of the systems approach in 7 CFR 319.56-75.

For each consignment treated in an irradiation facility outside the United States, a phytosanitary certificate, with the treatment section completed and issued by the NPPO, must accompany the consignment.

319.56-75(j) – Dosimetry Systems (business) – Dosimetry systems at the irradiation facility must indicate the doses need to ensure that all articles will receive the minimum dose required.

319.56-75(e) – Monitoring/Inspections at Port of Entry (business) – Treatment must be monitored by an inspector and will include inspection of treatment records and unannounced inspections of the facility by an inspector and may include inspection of articles prior to or after irradiation. Therefore, shipments of fresh mango fruit from Vietnam would be subject to inspection at the port of entry. This will provide an additional layer of phytosanitary protection in order to prevent the dissemination of plant pests into the continental United States.

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 no 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 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 90 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 its only source for the information and is not being collected through other forms or reports.

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.

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

Cooperative Hòa Lộc
Xã Hòa Hưng, Huyện Cái Bè, Tỉnh Tiền Giang
Director: Nguyễn Thành Nhơn
Tel/cell: 0919 592 221
Email: nhonhoaloc64@gmail.com

Cooperative Mỹ Xương
Số 637, Ấp Mỹ Thới, Xã Mỹ Xương, Huyện Cao Lãnh, Tỉnh Đồng Tháp
Director: Trần Long Châu
Tel/cell: 0673 924 486
Email: tranlongchaucl@yahoo.com

Cooperative Tân Thuận Tây
Tổ 5, Ấp Tân Chủ, Xã Tân Thuận Tây, Thành phố Cao Lãnh, Tỉnh Đồng Tháp
Director: Nguyễn Văn Chì
Tel/cell: 0167 424 7215
Email: leandongthap@yahoo.com.vn

APHIS' proposed rule (Docket No. APHIS-2016-0026) 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 the 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 Vietnam. The estimate of the annualized cost to respondents totaled \$7,225.

APHIS arrived at this figure by multiplying the total hours by the estimated average hourly wage of the above respondents. This hourly wage was provided by the IS attaché in Vietnam. (289 burden hours X \$25 estimated wage = \$7,225)

The estimated hourly wage was derived from the APHIS International Services attache.

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 \$12,245. (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.

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 included 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.