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# Operational Work Plan for the Import of Commodities from Ecuador Intended for Irradiation in the United States

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Effective Date: [March, 2018]

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## Summary

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This Operational Work Plan (OWP) was developed jointly by the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), and the Phyto and Zoosanitary Regulation and Control Agency (AGROCALIDAD)

Irradiation as a phytosanitary treatment is unlike conventional quarantine treatments in that the purpose of the treatment is to neutralize target pests. Therefore, "live," albeit mitigated, pests may be present post treatment. In order to ensure the phytosanitary risk has been adequately mitigated, the development of an Irradiation Program and application of an effective treatment requires a significant amount of cooperation between the participating entities.

This OWP describes requirements for import of products (articles) for quarantine irradiation treatment in the United States. Individual articles approved for entry under this Program are subject to conditions specified in a commodity-specific addendum to this OWP. This Work Plan applies only to the article(s) listed in the Addendum and does not authorize article(s) prohibited by APHIS regulations.


Product quality issues related to quarantine treatment application and non-phytosanitary related issues such as product marketing, sales, and distribution in the United States are outside the scope of APHIS regulatory authority. These business issues should be resolved between the Certified Treatment Facility and/or between commercial parties in Ecuador and the United States.

Deviation from these guidelines is not authorized unless both parties provide prior written approval. Each party retains the right to withdraw from this agreement upon written notice to the cooperating party's NPPO. This Work Plan will be in force until a new plan is approved and signed by all parties.

  
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Apr 3, 2018

Date

  
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20-03-2018

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## 1. Program Overview

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### 1.1 Commodities included in this program:

- 1.1.1 Commodities must be individually approved for entry under this Program and are subject to conditions specified in the commodity specific addendum.
- 1.1.2 Regulated quarantine pests associated with approved commodities, and required mitigation measures are listed in the commodity specific addendum.

### 1.2 Definitions

- 1.2.1 **Consignment** is the quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single Phytosanitary Certificate (PC). A consignment may be composed of one or more commodities or lots).
- 1.2.2 **Insect-proof package** is any package that is designed or constructed of material that prevents the entry and exit of insect pests. This may include any insect-proof box, carton, bag, or other container in which approved commodities are packed. Any openings for ventilation of the articles contained must be covered with a material with holes/openings no greater than 0.8 mm at the widest point. This is equivalent to a mesh size of no greater than 0.6 mm X 0.6 mm.
- 1.2.3 **Lot** is defined as the shipment of articles sent from a single Production Unit (see definition below) to a packinghouse in one day and assigned a reference number for traceability purposes.
- 1.2.4 **Neutralize** is a general term used to describe the mitigation effects of irradiation treatment on target pests. This term includes mortality, prevention of successful development such as non-emergence, inability to reproduce (sterility), or inactivation.
- 1.2.5 **Target quarantine pest** is a pest of quarantine significance that is known to be neutralized by an approved target dose of irradiation. Approved target doses and treatment requirements may be found in the PPQ Treatment Manual located on the Internet at:  
[http://www.aphis.usda.gov/import\\_export/plants/manuals/ports/index.shtml](http://www.aphis.usda.gov/import_export/plants/manuals/ports/index.shtml)
- 1.2.6 **Non-target quarantine pest** is a pest of quarantine significance that is not known to be neutralized by a given dose of irradiation. This may include, but is not limited to mites, mollusks, pathogens (viruses, diseases, nematodes), and adults and pupae of Lepidoptera.
- 1.2.7 **Production Unit** is a grove, orchard, greenhouse, or portion thereof, delineated by the National Plant Protection Organization (NPPO) of the country of origin as the traceable place of production for articles shipped under this Program.



1.2.8 **Program** is the systems, including products, processes, and policies, that allow for importation of regulated articles from a foreign country to the United States for application of irradiation treatment.

### 1.3 Participating Organizations

1.3.1 United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS)

1.3.2 Phyto and Zoosanitary Regulation and Control Agency (AGROCALIDAD)

1.3.3 Producers, Packers, and Exporters of approved Program commodities

### 1.4 Relevant Authority & Agreements

1.4.1 Commodities are subject to U.S. port of entry document verification and may be subject to monitoring, inspection and other actions at the ports of entry in the United States as deemed necessary by CBP, Food and Drug Administration (FDA), and other Federal or State regulatory agencies.

1.4.2 Commodities authorized under this Program are regulated under 7 CFR 305, Phytosanitary Treatments, Subpart 9, Irradiation Treatment Requirements, and 7 CFR Part 319, Foreign Quarantine Notices. Fruits and Vegetables are regulated under 7 CFR 319 Subpart 56. Articles moved within the United States for treatment as a condition of entry are subject to requirements of safeguarding regulations found in 7 CFR Part 352, Plant Quarantine Safeguard Regulations

1.4.3 Articles accompanied by any wood packaging material or unmanufactured wood articles are subject to ISPM 15 and USDA-APHIS regulations in 7 CFR 319 Subparts 40 (Logs, Lumber, and other Unmanufactured Wood Products) and 69 (Packing materials). Articles and conveyances are subject to inspection requirements as described in 7 CFR Part 330, Federal Plant Pest Regulations. These and other U.S. Regulations may be accessed at: <http://ecfr.gpoaccess.gov>

1.4.4 Importers must apply for and acquire a valid APHIS-PPQ Import Permit.

1.4.4.1 As a prerequisite condition of the application process for an Import Permit for irradiation of commodities upon entry, prospective importers must secure a valid APHIS-PPQ Compliance Agreement which specifies unique safeguarding and accountability requirements for overland movement of commodities from a port of entry to an APHIS Certified Irradiation Facility.

1.4.4.2 Detailed information on planning logistics and securing a Compliance Agreement for irradiation of imported commodities in the United States may be found at:  
[https://www.aphis.usda.gov/import\\_export/plants/plant\\_imports/irradiation/downloads/StepsforImporting.pdf](https://www.aphis.usda.gov/import_export/plants/plant_imports/irradiation/downloads/StepsforImporting.pdf)

1.4.4.3 APHIS-PPQ Import Permits should be secured at least 30 days prior to departure of the consignment. Permits will be provided only to a person or firm located in the United States able to accept liability and exercise responsibility for the consignment in the United States.

1.4.4.4 PPQ Import Permits can be obtained by contacting the Customer Support Unit at:

[http://www.aphis.usda.gov/import\\_export/plants/plant\\_imports/index.shtml](http://www.aphis.usda.gov/import_export/plants/plant_imports/index.shtml) or via telephone: (301) 851-2046 or (877) 770-5990 (Toll-free automated system), via fax: (301) 734-5786, or via email: [Permits@aphis.usda.gov](mailto:Permits@aphis.usda.gov)

## **2. Roles and Responsibilities of Participants**

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### **2.1 United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) will:**

- 2.1.1 Designate APHIS – International Services (IS) in Ecuador to serve as the liaison between Phyto and Zoosanitary Regulation and Control Agency (AGROCALIDAD) and APHIS Plant Protection and Quarantine (PPQ).
- 2.1.2 Provide technical and operational guidance to ensure phytosanitary security and Program integrity.
- 2.1.3 Provide guidance to the Department of Homeland Security (DHS) – Customs and Border Protection (CBP) to facilitate the authorized movement of the article from the port of arrival to the APHIS – PPQ Certified Treatment Facility.
- 2.1.4 Monitor the Treatment Facility(ies) in the United States to provide technical guidance and oversight to ensure treatment and safeguarding requirements are met and maintained.
- 2.1.5 Issue a treatment certificate for each consignment that successfully meets Program and phytosanitary irradiation dose requirements.
- 2.1.6 Conduct treatment facility certification, process configuration approval, and treatment audits.
- 2.1.7 Review requests and proposals for insect-proof packaging and configurations prior to use for proper construction and to ensure radiation doses are received by the articles contained within.



## 2.2 AGROCALIDAD will:

- 2.2.1 Serve as the primary contact point for and ensure compliance with all bilateral agreements and commitments including the Framework Equivalency Work Plan (FEWP), the Operational Work Plan (OWP) and associated Addenda, and other regulatory requirements for import of commodities for irradiation in the United States.
- 2.2.2 Serve as the liaison between APHIS and program participants in the country of origin to provide technical and operational coordination in the country of origin, with policy guidance from APHIS, to facilitate Program logistics and ensure phytosanitary security and Program integrity.
- 2.2.3 Establish a system to approve, register, and monitor certified production units and packinghouses which grow and pack articles under this Program.
- 2.2.4 For traceability purposes, assign a unique and permanent Production Unit Code (PUC) to each production unit and a Packinghouse Code (PHC) to each packinghouse participating in the Program.
- 2.2.5 At least thirty days before the beginning of shipment(s), provide APHIS (via official correspondence) the master list of the names of the participating production units and packinghouses and their corresponding traceability codes (PUC or PHC). In addition, addresses and contact information must be provided for each registered Packinghouse.
- 2.2.6 Pest management strategies to maintain low population levels of target and non-target pests, including a fruit fly trapping and management program as described in the Trapping Program Annex, are implemented by all registered program participants. Documentation associated with pest management and control must be made available to APHIS upon request.
- 2.2.7 Develop and sign written agreements with each registered packinghouse to ensure that at all times, articles intended for shipment to the United States under this Program are handled separately, are clearly labeled, and are physically segregated from products intended for other markets. These agreements must be provided to APHIS upon request.
- 2.2.8 Periodically visit, at least once per season, registered approved packinghouses to ensure compliance with these agreements, in particular requirements for phytosanitary safeguards and product traceability.
- 2.2.9 As designated in Addenda, sample, inspect, and issue Phytosanitary Certificates for all consignments that pass inspection. Phytosanitary Certificates must include traceability numbers for each lot(s) include in the consignment.

- 2.2.10 Ensure that all boxes exported strictly adhere to approved packaging and process configuration specifications.
  - 2.2.11 Have the capability and procedure in place to identify any plant pests detected during commodity inspections under the Program. Inspection results for each lot must be recorded in a ledger, database, or other means where the data may be retrieved, and must be provided to APHIS upon request.
  - 2.2.12 Ensure that a clearly marked sample pallet, representing 2% of the total consignment and comprised of at least one box from each lot in the consignment, accompanies each consignment.
  - 2.2.13 Trace back and investigate any packinghouse and/or production unit from where repeated incidents of target pests or significant detections of non-target pests have originated, and take appropriate regulatory action as described in Section 4. Noncompliance, Suspension, and Termination.
  - 2.2.14 Clean and inspect shipping containers both inside and out, including ventilation screens, prior to loading for export to ensure freedom from hitchhiking pests and contaminants.
  - 2.2.15 Notify APHIS with relevant information related to phytosanitary problems associated with the Program, and take corrective actions if necessary to preserve the integrity of the Program.
  - 2.2.16 Facilitate an annual training session for registered Program participants to describe Program requirements, parameters, and logistics in advance of and in order to prepare for each export season. APHIS may participate in this training session either voluntarily or upon request.
- 2.3 **Producers, Packers, and Exporters** of approved Program commodities will:
- 2.3.1 Cooperate with APHIS and AGROCALIDAD to facilitate implementation of program requirements.
  - 2.3.2 Comply with the conditions of this work plan, associated addenda and other regulatory requirements for import of commodities into the United States.





**Note:** Commercial parties in the country of origin and in the United States are responsible for coordinating and working with the Treatment Facility(ies) in the United States to establish packaging parameters for Program articles. Packaging parameters and process configurations are critical to proper delivery of target doses. These configuration parameters may include but are not limited to package size/shape/type, number of fruit per package, fruit size, gross weight of packages, and stacking configurations. The packaging parameters must be approved by APHIS-PPQ. Once approved by APHIS-PPQ, AGROCALIDAD must ensure that all participants strictly adhere to approved packaging and process configuration specifications.

### **3. Requirements for Entry into the United States**

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#### 3.1 Measures and Actions Applied in the Exporting Country

##### 3.1.1 Field/Greenhouse Crop Production Measures and Actions

3.1.1.1 All production sites intending to ship commodities to the United States for irradiation treatment must be individually registered and approved by AGROCALIDAD.

3.1.1.2 Each production site will be issued by AGROCALIDAD a unique and permanent Production Unit Code (PUC) which will serve as a traceability code for Program commodities.

3.1.1.3 Pest monitoring, management, and control strategies aimed at maintaining low pest populations, including a fruit fly trapping program, must be implemented in all production sites. AGROCALIDAD will periodically visit production sites and audit records, which may be provided to APHIS upon request. Harvested fruit must be placed in field bins or containers that are marked to show origin in a manner that enables traceback to the field.

3.1.1.4 Harvested fruit must be safeguarded against potential pest infestation with a pest-proof screen or plastic tarpaulin while in transit to the packinghouse and awaiting packing.

##### 3.1.2 Packinghouse Safeguarding Measures

3.1.2.1 All packinghouses intending to ship commodities to the United States for irradiation treatment must be individually registered and approved by AGROCALIDAD.

3.1.2.2 The AGROCALIDAD will issue each packinghouse a unique and permanent Packinghouse Code (PHC), which will serve as a traceability code for Program commodities.

3.1.2.3 Traceability must be maintained throughout the packing process.



3.1.2.4 Registered packinghouses may accept, pack, and store commodities destined to other markets, however all commodities intended for irradiation in the United States must be handled separately, packed at a different time(s) or on different days(s), and be stored physically separate from non-Program commodities.

3.1.2.5 Registered packinghouses must pack approved commodities only in APHIS-PPQ approved insect-proof packaging and in accordance with the packaging and process configuration parameters pre-established between industry and the Treatment Facility in the United States.

3.1.2.6 Registered packinghouses must ensure that before leaving the packinghouse, each package (or smallest containment unit) is in compliance with US Food and Drug Administration (FDA) labeling regulations. In addition, the Commodity name, Country of Origin, and PUC and PHC must be noted on each package.

3.1.2.7 Packed commodities not loaded or shipped within 24 hours of packing must be kept in a segregated cold storage room, or in a cold storage room segregated from non-Program commodities by at least 3 feet (1 meter).

### 3.1.3 Export Certification

3.1.3.1 Sampling, inspection, and export certification must be conducted in accordance with the Addendum.

3.1.3.2 Phytosanitary certificates must include traceability codes (PUC, PHC, and lot number(s) as appropriate to facilitate traceback) for all lots included in the consignment.

3.1.3.3 A sample pallet for port of entry clearance purposes must accompany each consignment. The sample pallet must:

- Represent 2% of the total consignment;
- Be comprised of at least one box from each lot in the consignment;
- Be clearly marked as "Sample Pallet" and;
- Be placed in the tailgate of the container to facilitate unloading and physical inspection, if warranted.

### 3.1.4 Loading and Shipping

3.1.4.1 All containers should be inspected prior to loading to ensure freedom from hitchhiking pests, debris, or other contaminants.

3.1.4.2 Wood packaging material including wooden pallets, if used, must be treated and marked per ISPM 15.

3.1.4.3 Care should be taken to minimize the possibility of container infestation during loading, for example:

- The loading area should be clean and clear of weeds;
- The container should seal properly against the loading dock of the packinghouse during loading;
- Avoid loading at night under lights which can attract flying insects

3.1.4.4 Phytosanitary safeguards, including insect proof packaging and container seals, must remain intact until arrival and port of entry clearance in the United States.

### 3.2 Measures and Actions Applied in the United States

3.2.1 CBP is responsible for conducting clearance at ports of entry for consignments intended for irradiation treatment in the United States. The CBP clearance process may include review and approval of import documents (including but not limited to import permit, phytosanitary certificate, transit permit, manifest, and invoices), verification of consignment contents, inspection of sample pallet for non-target pests, inspection of conveyance for hitchhiking pests and contaminants, and sealing of conveyance for transit purposes.

3.2.2 Any safeguards not found intact or paperwork errors may cause clearance delays.

3.2.3 Absence of the designated sample pallet, finding a non-target pest, or lack of proper labeling of the consignment is grounds for re-exportation or destruction of the consignment.

3.2.4 CBP will seal and authorize the movement of consignments from the port of entry to an APHIS-PPQ Certified Irradiation Treatment Facility for quarantine treatment. Products will not be released into commerce until quarantine treatment is complete and verified by APHIS-PPQ.

## 4. Noncompliance, Suspension, and Termination

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4.1 Any producer/production site, packinghouse, or exporter found not in compliance with the conditions of this work plan as determined by AGROCALIDAD and/or APHIS may be denied registration, approval, participation, and/or export certification services.

4.2 The AGROCALIDAD will document any apparent deficiencies and bring them to the attention of the registered packinghouse and/or or production units, who will be given the opportunity to correct any minor deficiencies and take remedial actions.

4.3 Actions to take based on interceptions in consignments during export inspection in Ecuador are noted in the Addendum.

- 4.4 If three or more lots from the same grower and/or packinghouse are rejected for export certification due to repeated interceptions of target or non-target pests:
- 4.4.1 The Production Unit and Packinghouse will be temporarily suspended pending an investigation by the AGROCALIDAD.
  - 4.4.2 Suspension may only be lifted after remedial actions to prevent recurrence have been implemented.
  - 4.4.3 If recurrence occurs, the Production Unit will be suspended for the remainder of the season.
  - 4.4.4 Any Production Unit or Packinghouse suspension must be reported to APHIS.
- 4.5 Actions to take based on interceptions of non-target pest(s) in consignments upon arrival in the United States:
- 4.5.1 The consignment will be rejected for entry and treatment.
  - 4.5.2 APHIS will notify AGROCALIDAD who will temporarily suspend fruit from export from the originating production unit, pending traceback and an investigation to determine the cause.
  - 4.5.3 APHIS may elect to participate in the investigation.
  - 4.5.4 A report of investigation must be provided to APHIS.
  - 4.5.5 Suspension will be lifted only after remedial actions to prevent recurrence have been taken.
  - 4.5.6 Subsequent interception(s) of the same pest will result in Program temporary Program suspension.
  - 4.5.7 In order to reinstate Program operations, APHIS and AGROCALIDAD will conduct a joint site visit audit to review operations and identify strategies to prevent recurrence and/or improve Program integrity.
  - 4.5.8 The Program may only be reinstated after remedial actions have been implemented, documented in writing, and reviewed by AGROCALIDAD and/or APHIS. Remedial actions may involve revisions to work plan and/or other import requirements.

## **5. Program Audit, Review, and Implementation**

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- 5.1 Independent of treatment oversight required by APHIS regulation and this work plan, APHIS will conduct audits (as necessary) of irradiation treatment operations and facilities in the United States.





5.2 Program operations in Ecuador will be reviewed and evaluated periodically by AGROCALIDAD to ensure that all aspects of operations and related activities are conducted effectively in accordance with this work plan, applicable guidelines, procedures, and standards.

5.3 APHIS reserves the right to request a program site visit audit in the event of noncompliance. APHIS costs associated with these audits may be supported by Industry via a Cooperative Services Agreement and cost recovery mechanism. Cooperator representatives may be included in the audits which will be coordinated with AGROCALIDAD.

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