



United States Department of Agriculture

US Phytosanitary Irradiation Program

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Science and Technology
Plant Protection and Quarantine
Animal and Plant Health Inspection Service
United States Department of Agriculture



“Any policy is a success by sufficiently low standards and a failure by sufficiently high standards.”
-Thomas Sowell

Outline

- PPQ Mission
- PPQ Organizational Structure
- General Information
- Regulatory Overview
- Program Types
- Close up on Preclearance
- Additional Resources





PPQ Mission

Regulate the movement of any commodity capable of harboring invasive, threatening plant pests, including noxious weeds, in order to protect the “agriculture, environment, and economy of the United States”

Facilitate import, export, and interstate commerce of agricultural products and other commodities that pose a risk of harboring certain plant pests

Plant Protection Act of 2000

PPQ Organizational Structure



Phytosanitary Irradiation

- APHIS treatments require an absorbed doses between 60-400 Gy
- FDA limits fresh fruit and vegetable treatments to 1000 Gy
- Irradiated food products must bear the Radura



Phytosanitary Irradiation

Treatment response options:

- Mortality
- Sterilization
- Inactivity or Devitalization
- Inability to Emerge/Fly



Mortality is usually not the target response for APHIS treatments and live insects may remain after treatment

Pest Proof Packaging



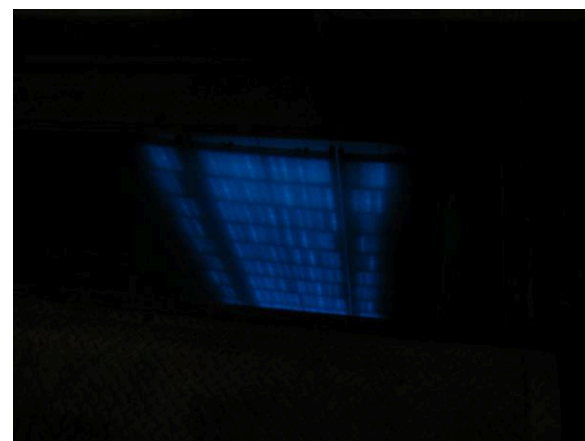
Pest Proof Packaging

- Packages with no holes can be used; all package seams must be taped
- Packages with holes can be used; pest proof mesh must cover all holes in; the mesh must be glued to the holes; all box seams must be taped
- Packages with or without holes can be used; commodity can be placed in pest proof bags inside of package; pest proof bag must be heat sealed or knotted
- Packages with or without holes can be used; package/pallet can be placed in pest proof bag; pest proof bag must be heat sealed or knotted (Preclearance Program Only)
- **Pest Proof Packaging must have mesh of size $\leq 0.6 \times 0.6$ mm, or pore size ≤ 0.8 mm (for largest dimension, i.e. the hypotenuse)**
- **Pest Proof Packaging cannot create a modified atmosphere around the commodity**

Phytosanitary Irradiation

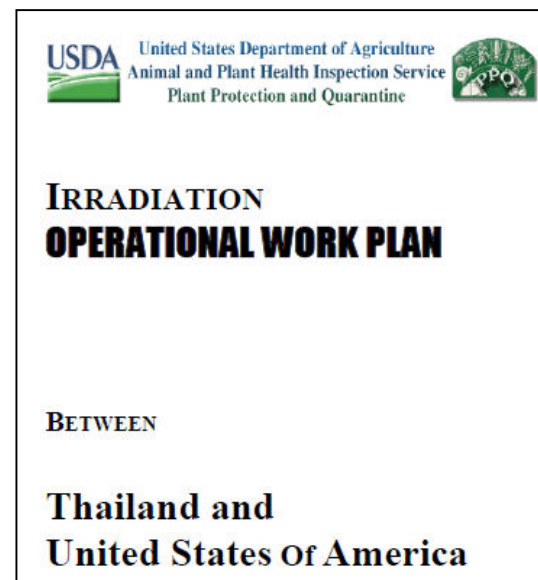
There are three approved source for phytosanitary irradiation treatments

- **Gamma:** Cobalt₆₀ or Cesium₁₃₇ emits photons during decay
- **E-beam:** High energy electrons propelled from an electron gun
- **X-ray:** High energy electrons are converted to X-rays (photons)



Regulatory Summary

- Market Access Granted
- Framework Equivalency Work Plan Signed
- Trust Fund Established
- Operational Work Plan Signed
- Commodity-Specific Addendum Signed



Regulatory Summary



- Facility Plan Approved
- Facility Certified
- Importer Compliance Agreement Signed
- Importer Permit Granted
- Packaging Approved
- Process Configuration Approved



Irradiation Program Types

Preclearance

Offshore Irradiation of U.S. Imports

Port of Entry

Domestic Irradiation of U.S. Imports

Domestic Quarantine

Treatment for Domestic Movement

Exports

Irradiation of U.S. Exports (in development)

Preclearance: India

Krushak

- First Overseas Facility
- Certified 2007
- Re-certified 2010
- Co₆₀
- Mango



Preclearance: Thailand

Synergy Health Ltd

- Certified 2008
- Re-Certified 2009
- Co₆₀
- Mangosteen and Longan

Thai Irradiation Center

- Certified 2007
- Re-Certified 2012
- Co₆₀
- Mangosteen and Longan



Preclearance: Vietnam



An Phu Irradiation

- Certified 2009
- Re-Certified 2012
- Co₆₀
- Dragon Fruit and Rambutan

Son Son Corporation

- Certified 2008
- E-beam
- Dragon Fruit and Rambutan

Preclearance: Mexico

Sterigenics

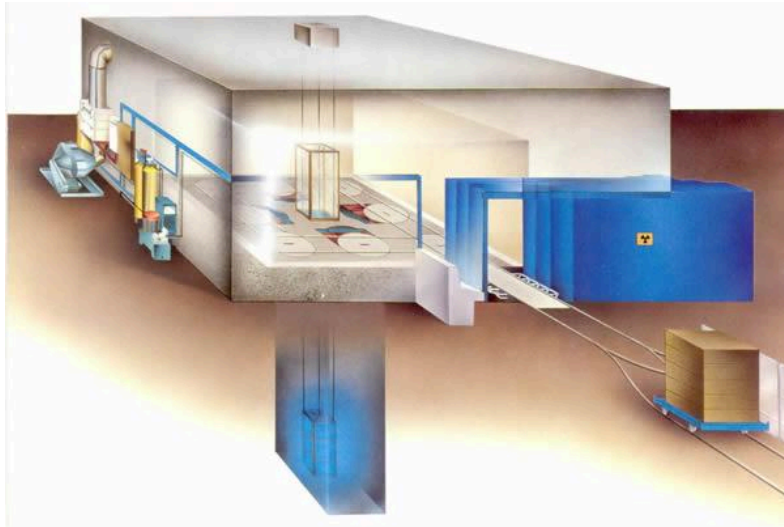
- Certified 2008
- Re-Certified 2012
- Co₆₀
- Guava and Chile Manzano

Benebión

- Certified 2011
- Co₆₀
- Guava, Chile Manzano, Mango, and Sweet Lime



Preclearance: South Africa



High Energy Processing (HEPRO)

- Certified 2012
- Co_{60}
- Grape



Preclearance Totals

(in kg)

	India	Mexico	South Africa	Thailand	Vietnam	Total
2007	0	0	0	195,000	0	195,000
2008	276,000	262,000	0	2,440,000	121,000	3,099,000
2009	132,000	3,559,000	0	2,247,000	117,000	6,055,000
2010	94,000	5,672,000	0	1,540,000	754,000	8,060,000
2011	80,000	5,539,000	0	743,000	1,445,000	7,807,000
2012	217,500	8,349,500	16,500	937,500	1,764,500	11,286,500
2013	283,000	9,526,000	16,500	1,060,500	1,967,500	12,853,500

Port of Entry



Sadex Corporation

- Certified 2009
- Sioux City IA
- Pakistan Mangos
- E-beam

Southern Tier Rule



<http://www.gpo.gov/fdsys/pkg/FR-2012-07-20/pdf/2012-17725.pdf>

Southern Tier Rule

As of July 2012, establishment of port of entry phytosanitary irradiation facilities are allowed in the Southern U.S. states.

Additional Requirements:

- Approval by State Representative to the National Plant Board (State Plant Regulatory Official)
- Refrigerated Conveyance of Commodity
- Maps of Surrounding Agricultural Production Areas
- Pest Trapping or Monitoring
- Additional Facility Safeguarding

Southern States: Port of Entry

NCEBR

- Certified 2012
- College Station TX
- Mexican Exports
- E-beam



Gateway America

- Certified 2013
- Gulfport MS
- South African Persimmon
- Co₆₀



Domestic Movement

Hawaii Pride

- 1st PPQ-Certified Facility
- X-ray
- Sweet Potato and Tropical Fruits



Pa'ina Hawaii

- Certified 2012
- Co₆₀
- Sweet Potato, Tropical Fruits and Herbs

U.S. Exports

Food Technology Service Inc.

- Mulberry FL
- Certified 2011
- Co₆₀
- Stone Fruit Exports to Mexico
- Domestic Movement of Grapefruit and Guava to Texas and California



U.S. Exports

Gateway America

- Gulfport MS
- Stone Fruit Exports to Mexico
- SAGARPA is considering recognizing the PPQ certification for their own program



Thailand Preclearance Program

Synergy Health Ltd

- Certified 2008
- Re-certified 2009
- Co60

Thai Irradiation Center (TIC)

- Certified 2007
- Co60



It's all about the "COOPERATOR."

The “Perks”



Thailand Preclearance Program

Eligible Commodities

- Dragonfruit
- Litchi
- **Longan**
- Mango
- **Mangosteen**
- Pineapple
- Rambutan





POP Officer Duties

Treatments

- Inspection- commodity, packaging and conveyance
- IRADS- certificate issuance

Packaging approval- data collection

Process configuration- data collection

Packinghouse inspections

Packing House Inspections



Thailand Preclearance Program



Inspection Report for Authorized Packinghouses, Irradiation Program, Thailand

<i>General Information</i>		
Packinghouse Name: SWIFT CO., LTD.	NPPO Issued Packinghouse Code (PHC):	
Location: 65/2 Moo 6 Tambon Donkhoi Kampaengsaen Nakompathom Thailand exotic@thaifreshproduce.com	Manager on Site: Sopsis Pimsongkroh Tel (66 34) 351025-6 Fax (66 34) 352576 email sopsis@thaifreshproduce.com	Inspection Date: July 11, 2012
	Officer Name: Laura Jeffers	

By signing below I acknowledge having read this report written by the above USDA Official who inspected the packinghouse and witnessed the packing process of fruit intended for irradiation.

Laura Jeffers

Digitally signed by Laura Jeffers
DN: cn=Laura Jeffers, o=USDA APHIS PPQ,
ou=CPHST,
email=laura.jeffers@aphis.usda.gov,
c=US
Date: 2012.07.11 19:45:48 -0400

Signature

Pest Exclusion Specialist
Name and Position/Title

July 11, 2012
Date

Below describe pertinent issues based on findings from Inspection Checklist

Brief History of Pack House


Facility has been open for 10 years. There is a stable workforce with little turnover. Facility provides yearly refresher training for staff. There are also large vegetable treatment (vaporheat/freeze) and packinghouse facilities co-located on site.

How many fruits are packed: 600 tons/year

How many Employees: ~50 people

To which countries are produce shipped: Fruits are shipped to **Japan, Korea**, New Zealand, and Australia (mango, mangosteen, longan, and pomelo). Officers from Japan and Korea are on site to supervise export treatments.

Inspection Checklist for Authorized Packinghouses Participating in Irradiation Program, Thailand

Documentation	Packinghouse operation has documented Standard Operating Procedures for packing program fruit		X
	Packinghouse has list of growers/production areas approved by the NPPO to produce fruit for irradiation program and issued a Production Unit Code (PUC)		X
	Packinghouse has written agreement(s) with treatment facility that fruit is destined		X
	Reliable system of trace-back (Please describe) from packinghouse to grower: Facility assigns a unique identifier to each lot associating it with the PUC.		X
Packinghouse Safeguards	Procedures in place for daily removal of culled fruit and other trash from the packinghouse		X
	Maintain general sanitation (pest control, cleanliness, and safeguards against infestation, such as screens, air curtains, double doors, IF preclearance inspection takes place at packinghouse): Monthly service (QC in place)		X
Receiving	Reliable system present for separating program and non-program articles		X
Packing Process	Fruit packed in pest-proof boxes. (If boxes have openings for ventilation they must be covered with a minimum 30 mesh screening)		X
	Program fruit is NOT packed at the same time as non-program fruit		X
Marking/ Labeling	The words "Treated with Radiation" or "Treated by Irradiation" printed on all boxes		X
	All boxes marked with International RADURA symbol: 		X
	Boxes also marked with:	• NPPO issued Production Unit Code (PUC) (sticker will be added)	X
		• NPPO issued Packinghouse Code (PHC) (sticker will be added)	X
	• Date of Packing (sticker will be added)	X	
Transportation to Facility	Program fruit is transported to irradiation facility in an enclosed conveyance		X
	Program fruit is NOT transported with non-program fruit		X

Treatment Duties

Inspection

- Commodity
- Packaging
- Conveyance

Review NPPPO/exporter paperwork

IRADS

- Approve treatment data
- Certificate issuance





Inspection

Instructions for Sampling

- Sampling Rate** Select 5 cartons of fruit for each lot.
- Selecting the Sample**
- The final lot size must be disclosed prior to initiating the sampling.
 - Each box, when packed, is numbered consecutively.
 - Samples will be collected according to the Sampling Spreadsheet attached and assembled onto an inspectional pallet. This pallet may be placed at the back of the truck and can be easily removed upon arrival at the inspection site.
- Procedure for Selecting The Cartons for Inspection**
1. Establish the lot size.
 2. Enter the number of boxes established in Step 1 into the Sampling Spreadsheet to determine the box numbers required for the sample.
 3. Complete the Sampling Worksheet. Attach a copy of this form to the sample boxes. Another copy of the form will be given to the Irradiation Facility personnel.

Sampling Spreadsheet

# of Boxes Total	Interval	First Box	Second Box	Third Box	Forth Box	Fifth Box
151	30.2	10	40	70	101	131

Inspection- Longans











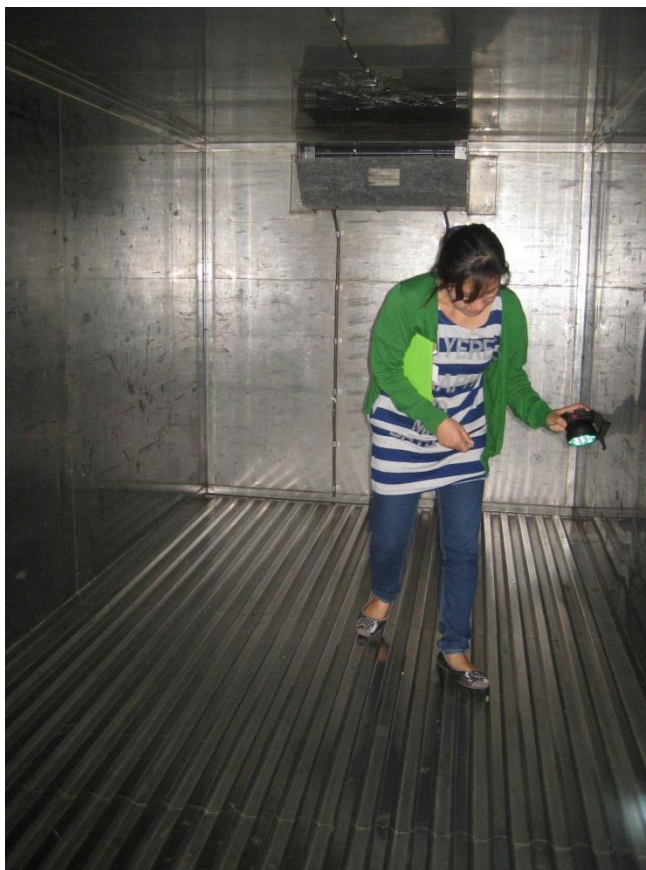
Inspection- Mangosteen

SYNERGY HEALTH (THAILAND) LTD. Chonburi, Thailand	
 14-2-00452-2-0004	
Treated by Irradiation	
FRESH MANGOSTEEN	
PUC: AC 03-02-3605-4436-126	TFC: 1003
PHC: AC 03-03-0132-1454-100	TIN: 2012 4133
Packing Date: 8 th August, 2012	Treatment Date: 9 th August, 2012
Lot Number: VTF017/08/12-MGT	





Inspection- Conveyance





Paperwork...

700/465 Moo 7 Tambol Donhuaroh
Amphur Muang, Chonburi 20000 Thailand

DOSIMETRY REPORT

Customer: Exoriens CO.,LTD. Batch Number: 2012 4133
 Product: Mangosteen (Box# 1) Specification Number: F-K436MTC0B1
 Customer Reference: N/A Dmin Factor: 0.632 Dmax Factor: 1.366
 Quantity: 150 boxes Min Dose Spec(kGy): 0.4 Max Dose Spec(kGy): 1
 Irradiation Date: August 9, 2012 Max Temp in Process (°C): na
 Instrument: Genesys 20
 Min Calculated Dose (kGy): 0.415 Max Calculated Dose (kGy): 0.897

Correction Factor: 1.00 Wavelength (nm): 552 Dosimeter Average Thickness (t): 0.0181
 Dosimeter Batch: B3 batch BD Calibration Date: 15-Sep-10 Initial Average Absorbance (Ao): 0.000
 Calibration ID: 3038-BD Dose Range: 0.205 to 1.991 kGy Software Version: 2.0

P8003	Max Temp	Dosimeter ID	Dosimeter Location	Irradiated Absorbance	Response (A1 - Ao) / t	Dose (kGy)	Adjusted Dose (kGy)
		Pallet#1	0001151	FA0	0.098	2.707	0.657
		Pallet#4	0009848	FA0	0.098	2.707	0.657
					0.000	na	

Dosimeter read out by: Pirapong T.
 Dosimeter released by: Pirapong T.

Date: 9/8/12, 13:45 hr.
 Date: 9/8/12

Review Treatment Data on IRADS



...paperwork...

DRAFT

DEPARTMENT OF AGRICULTURE
MINISTRY OF AGRICULTURE AND COOPERATIVES, BANGKOK, THAILAND

PHYTOSANITARY CERTIFICATE

THAILAND PLANT QUARANTINE SERVICE No. : 2230666
TO : PLANT PROTECTION ORGANIZATION OF UNITED STATES OF AMERICA

1. NAME & ADDRESS OF EXPORTER : บริษัท ไทยฟรุ๊ต จำกัด
EXPORTERS CO., LTD. 317 KAMOL RUDKORL RD., 18TH FLOOR, UNIT B, 38/004 RD., SILENG, BANGKRAE, BANGKOK 10609 THAILAND

2. DECLARED NAME & ADDRESS OF CONSIGNEE : Synergy Health
VANNA'S TROPICAL FRUITS & VEGETABLES, INC. 30420 NW 41ST STREET, SUITE 101-019, DORAL, FLORIDA 33174 USA.

3. NUMBER & DESCRIPTION OF PACKAGES : 150 CARTONS

4. DESTINATIONS MARKS : INVOICE NO. VTP017-01-12-1607, FDA REGISTRATION NO. 14191002204

5. PLACE OF ORIGIN : THAILAND

6. DECLARED MEANS OF CONVEYANCE : AIR

7. DECLARED POINT OF ENTRY : NAME, UNITED STATES OF AMERICA.

8. NAME OF PRODUCE AND QUANTITY DECLARED : MANGOSTEIN 1.000.000 KG (G) (FRESH MANGOSTEIN)

9. BOTANICAL NAME OF PLANTS : GARCINIA MANGOSTANA LINN.

10. DATE : 05 AUGUST 2012

11. TREATMENT : IRRADIATION

12. CHEMICAL (ACTIVE INGREDIENT) : --

13. DURATION & TEMPERATURE : --

14. CONCENTRATION : 40.00 GRAY

15. ADDITIONAL INFORMATION : --

16. STAMP OF ORGANIZATION : PLANT QUARANTINE RESEARCH GROUP, BANGKOK THAILAND

17. PLACE OF ISSUE : MR. CHAINARAT SORNSEI, PHU CHUP, PLANT QUARANTINE RESEARCH GROUP, PLANT QUARANTINE STATION

18. DATE : 05 AUGUST 2012

NOTE: No financial liability with respect to this certificate shall attach to the Ministry of Agriculture and Cooperatives, Thailand or to any of its officers or representatives of that Ministry.

Notification of Delivery Form for Fruit

To : Synergy Health (Thailand) Ltd. Fax : 038-717146 (Plant), 038-458435 (Office)
Contact : Khun Yuwadee (Order Administrator) Telephone : 038-450092-3, 038-458431-4 Ext. 112, 113

รูป / รูปถ่าย : EXCELLENCE CO., LTD.
โทรศัพท์ / เบอร์โทร : 02-631-2811 Fax / โทรสาร : 02-631-8812
ชื่อ - นามสกุล / ชื่อ-นามสกุล : ฐิติรัตน์ ภู่ ฐิติรัตน์ Position / ตำแหน่ง : --

) Delivery Date / วันที่จัดส่ง : 05 AUGUST 2012
) Product Type of Fruit / ชนิดผลไม้ : MANGOSTEIN
) Packing House Code (PHC) / รหัสโรงคัดบรรจุ : BC 0363 0102 1454 150
) Treatment Identification Number (TIN) / หมายเลขตรวจรังสี : 2112 4155

Remark : 1. Please fill in the data in English language
2. Please use 1 Sheet/ 1 Commodity/ 1 PHC/ 1 Flight 1 / 1

Lot no. / หมายเลข	Production Unit Code (PUC) / รหัสสวน	Grand total boxes of delivery (including boxes for sampling) / จำนวนกล่องรวมทั้งหมด (รวมกล่องเพื่อสุ่มตรวจ)		Weight / Box น้ำหนักกล่อง (กก)		Total Weight / รวมน้ำหนักทั้งหมด (G.W.)	Synergy Health (TH) / ซินเนอร์जी เฮลท์ (ไทย) การตรวจรังสี		Quantity for Irradiation / จำนวนที่พร้อมนำออกรังสี
		N.W.	G.W.	Total boxes for sampling / จำนวนกล่องเพื่อสุ่มตรวจ	Total boxes are re-packed after Sampling / จำนวนกล่องที่บรรจุใหม่หลังสุ่มตรวจ		Total Damage/ Abnormality boxes before Irradiation / จำนวนกล่องที่บกพร่องผิดปกติก่อนรังสี	Boxes / กล่อง	
LOT NO. 1A6	BC 0363 0102 4456 146	151	7	7.7	1,164.70				
Exp REF : VTP019/05/12 - MGT									
Grand Total Boxes/ รวมจำนวนทั้งหมด									

Delivery By / ส่งมอบโดย : ฐิติรัตน์ วันที่ : 05/08/12 Received By (Signature) / รับมอบโดย : _____ Date / วันที่ : _____

Exporter Forms

Thai Phytosanitary Certificate

World's Tiniest Snowman

**First and Last
Thai Snowman**





Process Configuration Approval



Packaging Approval Worksheet for Irradiation Treatments

This worksheet must be completed and approved for each package used for irradiation of articles in APHIS irradiation programs. All fields must be filled and the form must be signed by the appropriate officials prior to submission to TQAU for approval.

Item	Response
1. Name of package:	
2. Dimensions:	Length (cm): <input type="text"/> Width (cm): <input type="text"/> Height (cm): <input type="text"/> Total Volume (cm ³): <input type="text"/>
3. This packaging is best described as:	<input type="checkbox"/> Cardboard or paperboard box <input type="checkbox"/> Plastic, vinyl, or polystyrene clamshell <input type="checkbox"/> Mesh bag <input type="checkbox"/> Other (specify): <input type="text"/>
4. All holes in screens or other parts of the package have widths equal to or less than the limits in the addenda or operational workplan:	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Include as separate files digital photos of each side of the package, the interior, and any additional pictures that will help others identify the package.	

Completed By: Treatment Facility or Packaginghouse Official:

I certify that the information in this form is complete and correct and all packing materials described in this document conform to US Food and Drug Administration (FDA) standards for packaging materials for irradiated food described in 21 CFR 179.45. Signature: _____

Print Name: _____ Date: _____

Completed By: APHIS Official:

I have personally inspected the packing materials described in this document and found that they are insect proof and they meet the description supplied in this document. Signature: _____

Print Name: _____ Date: _____

Completed by TQAU:

This box was Approved Rejected for use in irradiation treatments. Signature: _____

Print Name: _____ Date Reviewed: _____
IRADS #: _____ Date Entered in IRADS: _____

Comments: If rejected, state reason here:

- Dimensions
- Material
- Insect-proofing
- Stored in IRADS

FDA maintains a list of approved materials for irradiation treatments



PPQ Irradiation Treatment Site

http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_plant_health%2Fsa_import%2Fsa_quarantine_treatments%2Fct_irradiation_treatment

I want to use irradiation as a treatment to import a commodity. Where do I start?

- FAVIR
- Commodity Import Request Process

I checked FAVIR. The commodity is eligible for entry, but irradiation is not listed as an approved treatment.

What do I do?

- Requires treatment- Paul Gadh (301) 851-2046
- Does not require treatment- Permit Services (301) 851-2046



PPQ Irradiation Treatment Site

I checked FAVIR. The commodity is eligible for entry, and irradiation is an approved treatment.

What are my options?

Option 1- Irradiation in the country of origin under an established preclearance program

Preclearance programs- Vedpal Malik (301) 851-2278



PPQ Irradiation Treatment Site

Option 2- Irradiation conducted at the Port of Entry in the United States

- Importer Compliance Agreements- Roger Holman (919) 855-7336
- Import Permits- Permit Services (301) 851-2046
- Packaging Logistics- Laura Jeffers (919) 855-7455



PPQ Irradiation Treatment Site

I am interested in having an irradiation facility certified by APHIS to apply quarantine treatments for fresh fruits and vegetables.

Where can I get more information?

Facility Approval and Certification

Laura Jeffers (919) 855-7455

laura.a.jeffers@aphis.usda.gov

PPQ Irradiation Treatment Site

Are there non-phytosanitary import requirements that I should be aware of?

- Food and Drug Administration:
<http://www.fda.gov/>
- Department of Homeland Security, Customs and Border Protection Agency:
<http://www.cbp.gov/>
- Agricultural Marketing Service:
<http://www.ams.usda.gov/>

Questions?

