US Phytosanitary Irradiation Program

Woodward D Bailey

Laboratory Director Miami, FL US

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

Field Operations Rebecca Bech, Associate Deputy Administrator Matthew Royer, Executive Director

- Operational Director South West
- -AZ, AR, CA, NM, OK, LA, TX

AL/MS, MD, WV

- -ESF 11; VMO; Data Management
- Operational Director South East
 -DE, GA, PR, NC/SC, TN/KY, VA, FL,
- -SITC; Imports/Exclusion; Plant Germplasm
- Operational Director North East
- -CT/MA/RI, ME, MN, NJ, NY, PA, VT/NH, WI, MI, IN, OH, IL
- -Predeparture; Biotech; Exports; Trade
- . Operational Director North West
- -AK/WA, CO, HI, ID, IA, MO, MT, ND, NE/KS, NV/UT, OR, SD, WY
- -Detection and Response
- OD Pest Management/Safety
- -Pest management; Aircraft Operations; Safety and Health
- Administrative Support

Osama El-Lissy Deputy Administrator

Phytosanitary Issues Management International Plant Health Standards AQI User Fee Outreach and Communications Chief of Staff

Science and Technology

David Kaplan, Associate Deputy Administrator Phil Berger, Executive Director

- Center for Plant Health Science and Technology
- echnology
- National Clean Plant Network
- PPQ Representative on Climate Change; Plant Health Quadrilaterals Science Collaboration Working Group; Coordinating Office for Science and Technology Assessment; European Phytosanitary Research
- Administrative Support

Policy Management Jeff Grode,

Associate Deputy Administrator Mike Watson, Executive Director

- · Resource Management and Planning Staff
- Professional Development Center
- -Cooperator Training Unit
- -Field Operations Training Support
- -National Detector Dog Training Center
- Plant Health Programs
- -Regulations, Permits, and Manuals
- -Preclearance & Offshore Programs
- -Quarantine, Policy, Analysis, and Support
- -Pest Detection and Emergency Programs
- -Pest Management
- -Select Agent Program
- -Export Services
- Business Information Systems Strategy and Management
- Administrative Support

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 ≤ 0.6 x 0.6mm, or pore size ≤ 0.8mm (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



IRRADIATION
OPFRATIONAL WORK PLAN

BETWEEN

Thailand and United States Of America

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

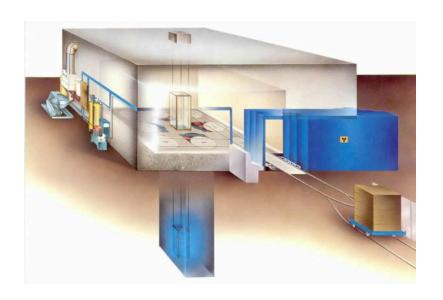
- Certified 2008
- Re-Certified 2012
- Co₆₀
- Guava and Chile Manzano

Benebión

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



Preclearance: South Africa



High Energy Processing (HEPRO)

- Certified 2012
- Co₆₀
- 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

General Information		
Packinghouse Name: SWIFT CO., LTD.		NPPO Issued Packinghouse Code (PHC):
Location: 65/2 Moo 6 Tambon Donkhoi Kampaengsaen Nakompathom Thailand	Manager on Site: Sopis Pimsongkroh Tel (66 34) 351025-6	Inspection Date: July 11, 2012
exotic@thaifreshproduce.com	Fax (66 34) 352576 email sopis@thaifreshproduce.com	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 ou-USDA APHIS PPQ, ou-CPHST, ou-USDA APHIS PPQ, ou-CPHST, omail-laura_ajeffers@aphis.usda.gov,		
C=US Date: 2012.07.1119:45:48 -04'00'	Pest Exclusion Specialist_	July 11, 2012
Signature	Name and Position/Title	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

Digitally signed by Laura Jeffers

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			
	Packinghouse has list of gro and issued a Production Uni	wers/production areas approved by the NPPO to produce fruit for irradiation program t Code (PUC)	X	
	Packinghouse has written ag	reement(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.			
Packinghouse Safeguards	Procedures in place for daily	removal of culled fruit and other trash from the packinghouse	X	
Saleguarus	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)			
Receiving	Reliable system present for separating program and non-program articles			
Packing Process	Fruit packed in pest-proof bo 30 mesh screening	oxes. (If boxes have openings for ventilation they must be covered with a minimum	X	
	Program fruit is NOT packed at the same time as non-program fruit			
Marking/ Labeling	The words "Treated with Radiation" or "Treated by Irradiation" printed on all boxes			
Luctung	All boxes marked with International RADURA symbol:			
	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	Program fruit is transported	to irradiation facility in an enclosed conveyance	X	
to Facility	Program fruit is NOT transp	orted with non-program fruit	X	

Treatment Duties

Inspection

- Commodity
- Packaging
- Conveyance

Review NPPO/exporter paperwork

IRADS

- Approve treatment data
- Certificate issuance





Inspection

			Instructions fo	r 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.					
		Enter the number of boxes established in Step 1 into the Sampling Spreadsheet to determine the box numbers required for the sample.					
		 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 Spr	eadsheet			
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

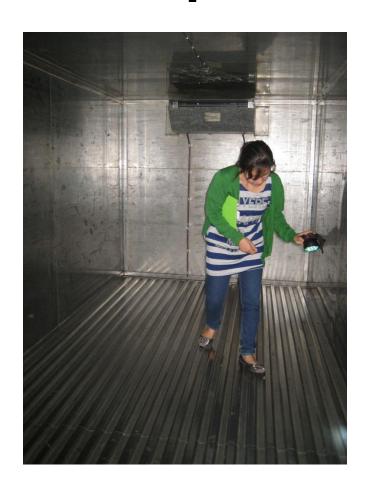








Inspection- Conveyance







Paperwork...

actor: 1.366 kGy): 1
kGy): 1
kGy): 0.897
(Ao): 0.0181 (Ao): 0.000 sion: 2.0 1
ţ

Review Treatment Data on IRADS



...paperwork...

rom / จากบริษัท

elephone / wszlinz :

WINDLESSER

CAT NE. 146

EXC REF: VTFOIS /08/12-MST

lame - Surname / र्नेश-प्राधानात :

) Delivery Date / วันที่สากสโม

Product Type of Fruit / TURES LE

Packing House Code (PHC) / วทัสโรงทัศบรรจ

Treatment Identification Number : TIN) / หมาธมสรากวราธริงสี) Description of Fruit / รายตะเลียดรองผลไม่ที่จัดตง :

AC 0354 9105 4496 141

Synergy Health (Thailand) Ltd.

Contact: Khun Yuwadee (Order Administrator)

	NEWS THE PARTY OF	an construction	
3400	PEPARTMENT (STRY OF AGUICULTURE AND C	DF AGRICULTURE COPERATIVES, BANGKOK, 110	ALAND
		RY CERTIFICATE	
THAILAND PLANT QUARANTINE SE To : PLANT PROTECTION ORGANIZA		AMERICA	No.: 3233666
1. NAME & ADDRESS OF EXPORTE		S. DECLARED NAME & ADDI	RESS OF CONSIDNERS.
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	THESERY	p	
3. NUMBER & DESCRIPTION OF PA	CKAGES:	4. DEVENGUISHING MARKS	
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E. PLACE RECOUGES:		6. DECLARED MEANS OF	T. DECLARED PODET OF
THAILAND		CONVEYANCE:	TINTEY : MIAMI , INITED STATES OF AREACA.
B. NAME OF PRODUCE AND QUANT	TTY DECLARD	9. BUTWINGAL NAME OF PLA	MIS:
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manual wine

Notification of Delivery Form for Fruit

EXCRIENS a. LID.

9 AUGUST 2012

(including boxes for

sampling) /

จำนวนกลองทั้งหมด triainensolegas N.W. G.W.

MANGOSTEEN

Customer fill in / ลูกคากขอกขายละเอียด Production Unit Code (PUC)/ Grand total boxes of 038- 717146 (Plant), 038-458435 (Office)

04-631-2812

Remark: 1. Please fill in the data in English language

Synorgy Health (ส in / ชินเนอร์จี เฮลท์ กรอกรายคะเอียล

Total Damage/

Abnormality

boxes before

Irradiation /

ความผิดปกติก่อน

Refure

วันที่

2. Please use 1 Sheet/ 1 Commodity/ 1 PHC/

จำนวนที่พรอมฉายรังสึ

Boxes /

Total Gross

น้ำหน้าพ้งหมด

(G.W.)

Telephone: 038-450092-3, 038-458431-4 Ext. 112, 113

Fax / Living

Weight/ Box Total Weight / Total boxes Total boxes

(G.W.) 4mmunees

เพื่อสมครวจ จำนวนกลอง

พีนระชากน

พด็วสมสราจ

Grand Total Boxes/ รวมจำนวนทั้งหมด

น่าหนักกายคง รามน้ำหน้าทั้งห for sampling

Position / Mnumus

Thai Phytosanitary Certificate

Exporter Forms

AC 0303 0138 1454 100



...and more paperwork...

U.S DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NO.		2. COUNT	RY OF GRIGIN
PLANT PROTECTION AND QUARANTIVE	4783	pg. 1 of 1)	Thelland	
FOREIGN SITE CERTIFICATE OF INSPECTION	3. DATE LIDADED		4. FOREIG	N PORT OF EXPORT
AND/OR TREATMENT	08/09/2012		Suvereb	humi Altport, Samulpi
CARRIER IDENTIFICATION			4. U.S.PO	RT OF ENTRY:
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7. BHPPER (Were see Address—Induse Zip Code) Epotiens 517 Karndisskosol Building, 10th Floor Bangrisk, Bangkok, Bangkok Theiland	8 CONSIGNEE (Name VANNA'S TROPIC 10480 DORAL BL/ DORAL, Florida US	AL FRUITS. AD., STE 10	AND VEGE	
a. COMMODITY	10. NO. CONTAINER [Identity as box, sock, 1/2 throse box, fat, cardboard box, etc.]		11, CON IDENTIFICA	NTAINER TION MARKS
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PUC: AC 03-02-0606-4436-120 PHC: AC 03-03-0132-1456-100				
2. LOCATION OF INSPECTION AND/OR TREATMENT TFC#: 1803, Synorgy Health (Theiland) Ltd: Amphir Muang, Chon Burl, Theilan	sd.	13 DATE 08/09/201	2	
his certifies that the shipment described above has been inspected and nity into the United States.	stroccos ni betsent rold	nce with ac	ricultural i	equirements for
4. SIGNATURE OF PLANT PROTECTION AND QUARAFTINE OFFICER LIBURI JOHEN		15, DATE(5 06/09/201		
reated with Irradiation **O POYM 203 NA. 2017)				page 1 of 1

PPQ 203

World's Tiniest Snowman

First and Last Thai Snowman





Process Configuration Approval

USDA	
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 TOALI for appropria

Item	Response
Name of package:	
2. Dimensions:	Length (cm): Width (cm): Height (cm): Total Volume(cm ²):
 This packaging is best described as: 	Cardboard or paperboard box Plastic, vinyl, or polystyrene clamshell Mesh bag Other (specify)
 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: 	Yes No
Include as separate files digital photos of that will help others identify the package.	each side of the package, the interior, and any additional pictures
	ouse Official: uplete and correct and all packing materials described in this inistration (FDA) standards for packaging materials for irradiated

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:
The USDA is an equal opportunity provider and employer. Distance 1918/2010 Revision: Original Ver. TURNA-074 Page 1 of 1
WS-1-14-4-234 WS-1-14-4-234 Printed copies of this document are considered for reference only. It is the responsibility of employees to ensure that they are using the correct version of this document by checking the document revision level with that haid in the TOALI Document Repository as listed in WT-MS-XX-001.

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

FDA maintains a list of approved materials for irradiation treatments

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

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

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

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

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

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



Questions?

