USDA
United States Department of Agriculture

USDA-APHIS-PPQ Irradiation Program: Current Status

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Outline

- Regulatory summary
- Program types
- Southern states rule
- Process configuration testing
- Other needs
- Phytosanitary irradiation resources

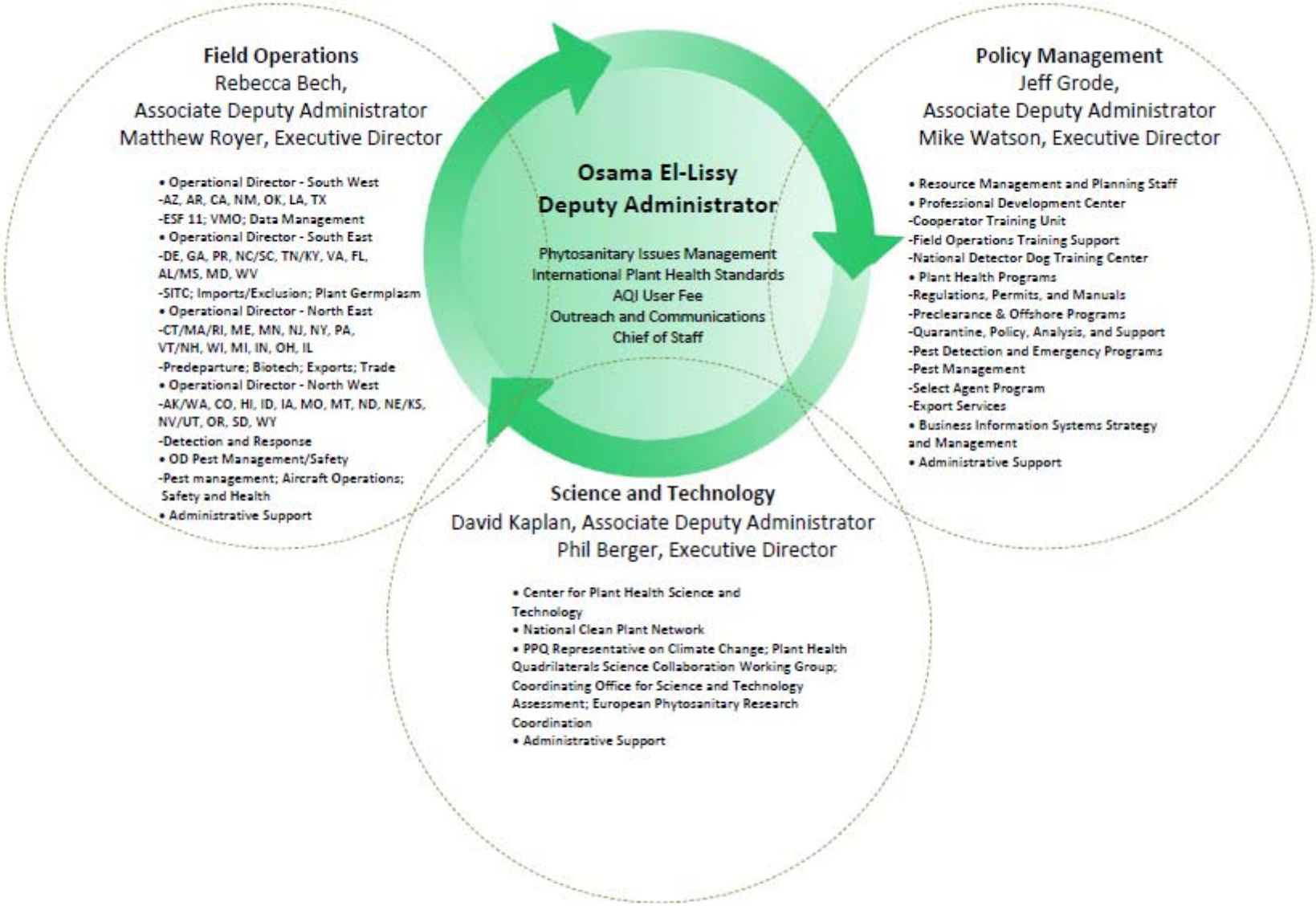
PPQ Mission

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

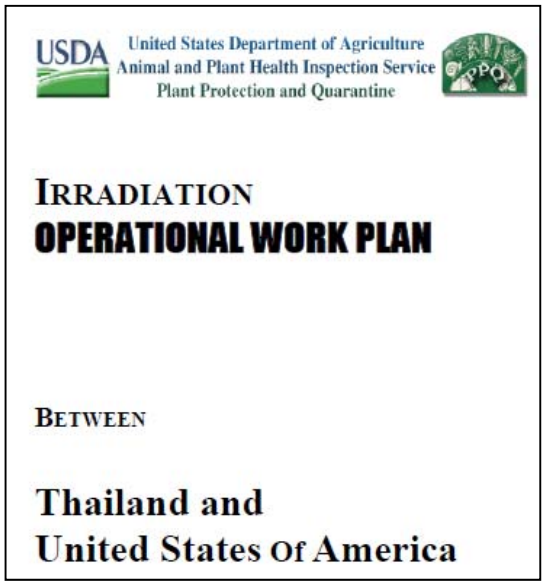
Plant Protection Act of 2000

PPQ Organizational Structure



Regulatory Summary

- Market access granted
- Framework equivalency work plan signed
- Trust fund established
- Operational work plan signed
- Commodity-specific addendum signed


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

IRRADIATION
OPERATIONAL 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

Phytosanitary Irradiation

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

Irradiation Program Types

Preclearance

- Offshore irradiation of US imports 

Port of Entry

- Domestic irradiation of US imports 

Domestic Quarantine

- Treatment for domestic movement

Exports

- Domestic irradiation of US exports (in development)

Preclearance: India

Krushak

- First overseas facility
- Certified 2007
- Re-certified 2010
- Co_{60}
- Mango

Preclearance: Thailand

Synergy Health Ltd

- Certified 2008
- Re-certified 2009
- Co_{60}
- Mangosteen, longan

Thai Irradiation Center

- Certified 2007
- Recertified 2012
- Co_{60}
- Mangosteen, longan

Preclearance: Vietnam

An Phu Irradiation

- Certified 2009
- Recertified 2012
- Co_{60}
- Dragon fruit and rambutan

Son Son Corporation

- Certified 2008
- E-beam
- Dragon fruit and rambutan

Preclearance: Mexico

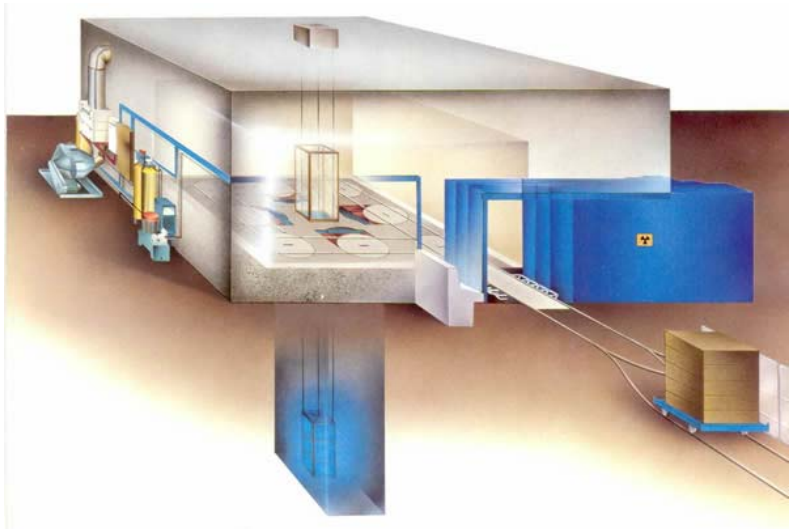
Sterigenics

- Certified 2008
- Recertified 2012
- Co_{60}
- Guava and chile manzano

Benébion

- Certified 2011
- Co_{60}
- Guava, chile manzano, mango, and sweet lime

Preclearance: South Africa



High Energy Processing (HEPRO)

- Certified 2012
- Co_{60}
- Grape

Preclearance Totals

(in kg)

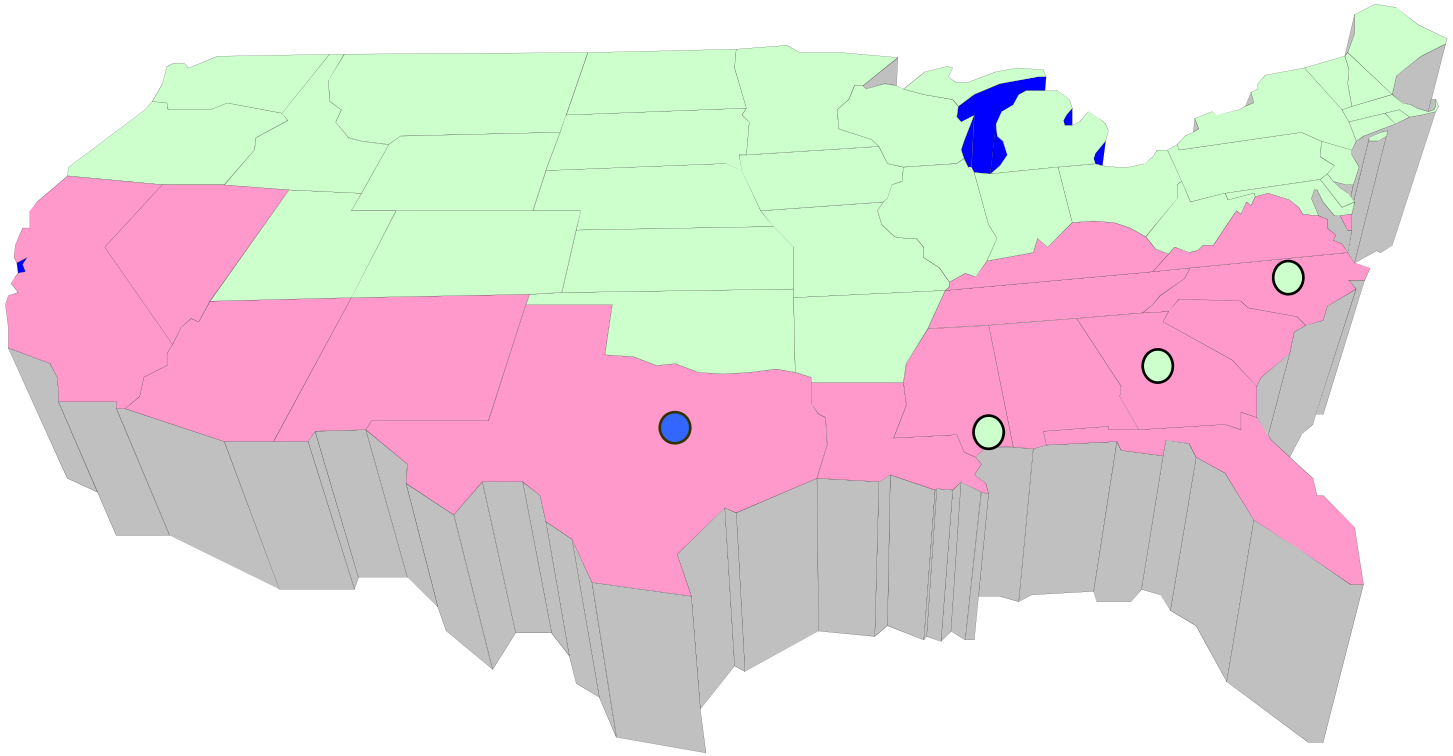
	India	Mexico	South Africa	Thailand	Vietnam	Total
2007	0	0	0	195,000	0	195,000
2008	276,000	262,000	0	2,440,000	121,000	3,099,000
2009	132,000	3,559,000	0	2,247,000	117,000	6,055,000
2010	94,000	5,672,000	0	1,540,000	754,000	8,060,000
2011	80,000	5,539,000	0	743,000	1,445,000	7,807,000
2012	217,500	8,349,500	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 US: Port of Entry

NCEBR

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

Gateway America

- Certified 2013
- Gulfport MS
- South African persimmon
- Co_{60}

Southern US: Port of Entry

Test shipment

- South African persimmons
- Gateway America
- MOR USA, Inc

Capetown
South Africa
→ AIR →
Houston
TX
→ BONDED TRUCK →
Gulfport
MS

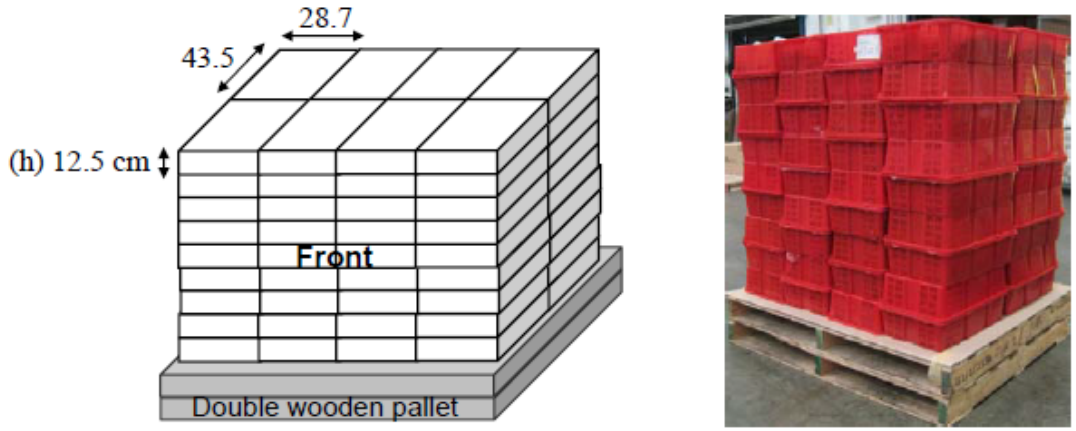
Southern US: Port of Entry

Port of Entry issues

- Additional safeguarding at the facility
- Pre-approve packaging
- **Process configuration approval upon arrival**

Process Configurations

Packaging dimensions and orientation are critical when delivering an absorbed dose within a tight range

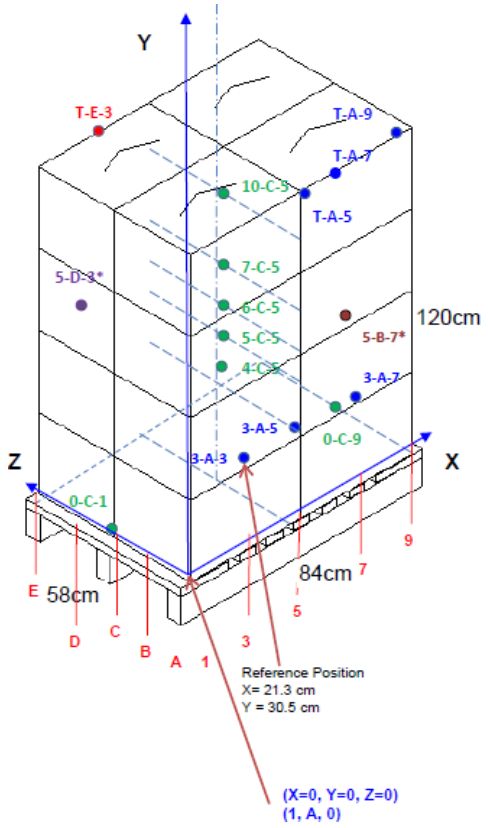


Dose Mapping

It is important to know what the absorbed dose range will be throughout the configuration

Dose mapping

- Identify areas of high and low absorbed dose
- Determine R_f (reference dose)



Research and Regulatory Needs

- Continue Process Configuration Testing
- Generic Doses
- Quality Studies
- Irradiation Treatment Validation 
- Modified Atmosphere Packaging 

Irradiation Treatment Verification

In the event that CBP intercepts a live pest within the pest proof packaging, PPQ needs a tool to verify that an irradiation treatment has occurred.

Ideally, the verification tool would:

- Provide immediate Y/N answer
- Be inexpensive
- Be easy to use
- Not require hazardous reagents
- Have low-maintenance storage requirements
- Work for multiple insect families

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control num ber. The valid OMB control numbers for this information collection are 0579-0190 and 0117 3. The time required to complete this information collection is estimated to a verage .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completi ng and reviewing the collection of information.

OMB APPROVED 0579-0190 and 0173

U.S DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

FOREIGN SITE CERTIFICATE OF INSPECTION AND/OR TREATMENT

1. CERTIFICATE NO. 3517 (pg. 1 of 1)
2. COUNTRY OF ORIGIN: Viet Nam
3. DATE LOADED: 12/15/2011
4. FOREIGN PORT OF EXPORT: Tan Son Nhat Airport, VN
5. CARRIER IDENTIFICATION: CX 094
6. U.S. PORT OF ENTRY: JFK Airport, NY
7. SHIPPER (Name and Address - Include Zip Code): ALO GREEN COMPANY LIMITED 2/261 NGUYEN GIA THIEU STREET, WARD 6, DISTRICT 3 HO CHI MINH CITY, Ho Chi Minh (mncpity) Viet Nam
8. CONSIGNEE (Name and Address - Include Zip Code): RESOURCE CREATION LLC 1806 FLORAL DR WILMINGTON, Delaware USA

9. COMMODITY	10. NO. CONTAINERS (Identify as box, sack, 1/2 Bruce box, flat, cardboard box, etc.)	11. CONTAINER IDENTIFICATION MARKS
1. Dragon Fruit (Hylocereus Spp.) TRT: 3910; Lot:AG1112005 FTID: 2011120023; Dmin: 409.36	200 / 400 boxes	AKE 39083 CX (41875 - 41876)
PUC: AA.03.01.03.001 PHC: 001		
2. Dragon Fruit (Hylocereus Spp.) TRT: 3910; Lot:AG1112005 FTID: 2011120023; Dmin: 409.36	200 / 400 boxes	AKE 39639 CX (41877 - 41878)
PUC: AA.03.01.03.001 PHC: 001		

12. LOCATION OF INSPECTION AND/OR TREATMENT: TFC#: 1004; Son Son Corporation: Ho Chi Minh City, Ho Chi Minh (mncpity), Viet Nam.
13. DATE: 12/15/2011

This certifies that the shipment described above has been inspected and/or treated in accordance with agricultural requirements for entry into the United States.

14. SIGNATURE OF PLANT PROTECTION AND QUARANTINE OFFICER: Robert Guillermo
15. DATE ISSUED: 12/15/2011

Treated with Irradiation

page 1 of 1

PPQ FORM 203 (JUL 2007)

USDA
United States Department of Agriculture

Irradiation Treatment Verification

CPHST has just initiated a cooperative agreement with the University of Florida to develop a diagnostic assay to verify that a phytosanitary irradiation treatment was performed using commercially available antibodies to biochemical products of irradiation stress.

APHIS

UF | UNIVERSITY of FLORIDA

Modified Atmosphere Packaging

MAP is a process that alters the gas composition surrounding a commodity

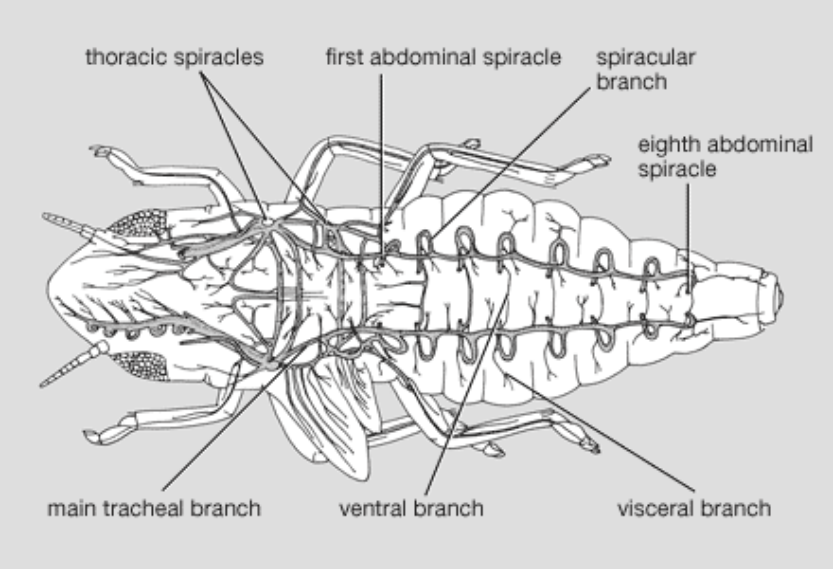
- prolongs the shelf-life of perishable goods
- slows the speed of aerobic microorganisms
- low O_2 environments are created by displacing O_2 in the packaging with other gases (e.g. N_2 or CO_2)

In the past few years, requests to use MAP for phytosanitary treatments have dramatically increased.

Modified Atmosphere Packaging

Most MAP creates a low O_2 environment

Respiration slows, resulting in reduced O_2 concentrations in the hemolymph



In hypoxic environments,
higher absorbed doses may be necessary to achieve same physiological effects

Modified Atmosphere Packaging

Commodity	Temperature [°C]	Humidity [%]	Modified atmosphere % O_2	CO_2
Fruit				
Apricot	0-5	90	2-3	2-3
Orange	3-9	90-95	5-10	0-5
Banana	13-15	90-95	2-5	2-5
Persimmon	0-5	90-95	3-5	5-8
Cherry, sweet	0-5	90-95	3-10	10-15
Strawberry	0-5	90-95	4-10	15-20
Apple	0-5	90	1-3	1-3
Blueberry	0-5	90-95	5-10	15-20
Peach	0-5	90-95	1-2	3-5
Pear	0-5	90-95	2-3	0-1
Vegetables				
Asparagus	0-5	95-100	aria	5-10
Broccoli	0-5	95-100	1-2	5-10
Cauliflower	0-5	95-98	2-5	2-5
Cucumber	8-12	90-95	3-5	0
Lettuce	0-5	95-100	1-5	0
Corn, sweet	0-5	95-98	2-4	10-180
Green pepper	8-12	90-95	3-5	2-8
Tomato, partly	8-12	90-95	3-5	0-3
Spinach	0-5	95-98	7-10	5-10

Table 8: MAP recommended conditions for fresh fruit and vegetable

Modified Atmosphere Packaging

CPHST is funding University of Florida research to characterize the effects of modified atmospheres on irradiation treatments

- Determine whether irradiation in modified atmospheres affects survival or fertility (Lepidopteran pests)

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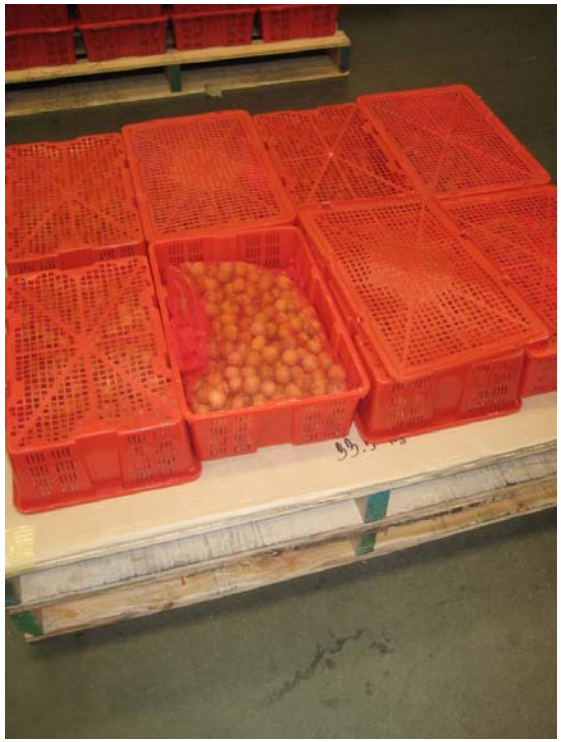
Pest Proof Packaging



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

Fresh Fruits and Vegetables Import Manual

http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/fv.pdf

FAVIR

https://epermits.aphis.usda.gov/manual/index.cfm?ACTION=pubHome

PPQ Treatment Manual

http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf

PPQ Stakeholder Registry

https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new

Final Thoughts & Questions