



## **IRRADIATION PLANTS IN MANGO PRODUCING COUNTRIES**

### **1. INTRODUCTION**

Mangos must go through a specific phytosanitary protocol approved by the U.S. Department of Agriculture's Animal Plant Health Inspection Service (USDA-APHIS) before they are exported to US. The protocol is a designed to prevent the introduction of quarantine pests into the United States. The most common APHIS approved protocol for mangos has been hot water treatment; however, APHIS has approved protocols to allow for the irradiation of certain mangos for export into the United States.

### **2. BRAZIL**

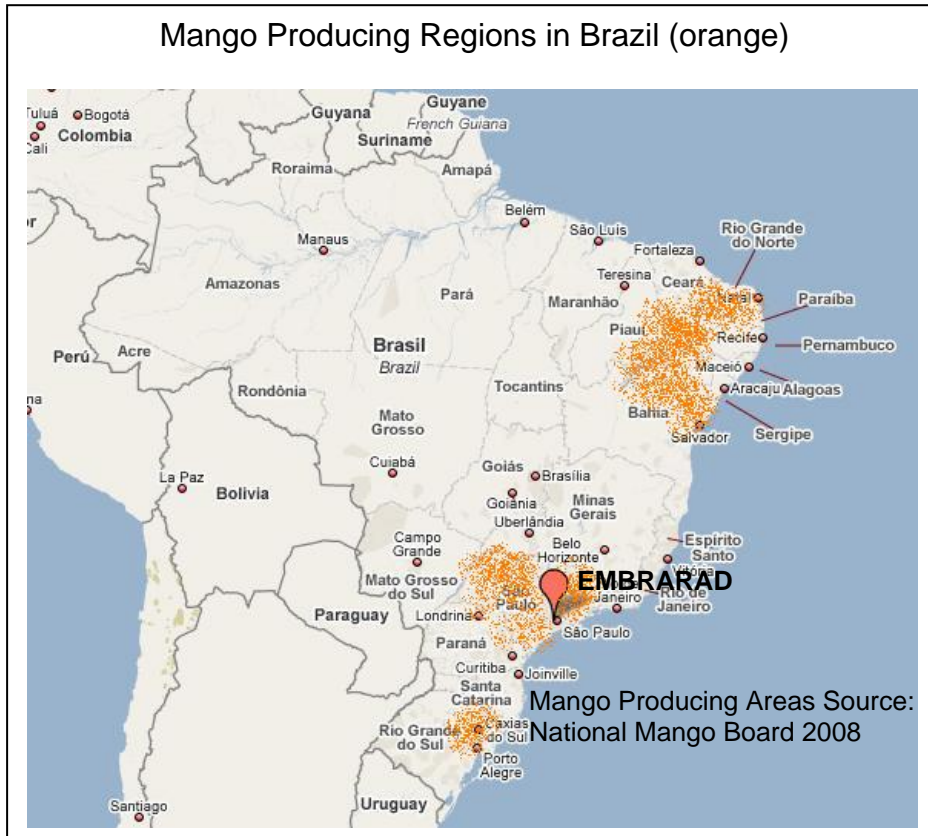
According to the NMB there is one irradiation plant in Brazil, EMBRARAD, but it doesn't irradiate fresh fruits, it only works with spices and surgical materials.

#### **2.1 EMBRARAD**

Empresa Brasileira de Radiações (EMBRARAD) is the only irradiation plant working in Brazil. They don't irradiate fresh fruit; they work only with spices and surgical materials.



## 2.2 LOCATION



## 2.3 SOURCE

EMBRARAD

Dr. Dirceu Vizeu,

Director

Av. Cruzada Bandeirantes, 269

Coita, SP CEP: 06700-000

Brazil

[www.embrarad.com.br](http://www.embrarad.com.br)

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## 2.4 USDA GUIDELINES RELATED TO IRRADIATED MANGOS FROM BRAZIL

According to the Fresh Fruits and Vegetables Import Manual (Attachment 2), irradiation as an optional treatment is available only after an exporting country



has entered into a framework equivalency work plan agreement and met other requirements as specified in 7CFR 305.2. (Appendix B). Currently, Brazil has not entered into a work plan agreement. Fruits irradiated in the country of origin and accompanied by the Plant Protection and Quarantine (PPQ) form 203 to confirm irradiation may enter any state in the U.S. However, untreated fruits and vegetables, intended to be irradiated for quarantine pests, cannot be treated within nor transit through the following states: Alabama, Arizona, California, Florida, Georgia (except for treatment in Atlanta, GA), Kentucky, Louisiana, Mississippi (except for treatment in Gulfport, MS), Nevada, New Mexico, North Carolina (except for treatment in Wilmington, NC), South Carolina, Tennessee, Texas (except untreated products to be irradiated may transit through Dallas/Ft. Worth) and Virginia.

### **3. ECUADOR**

According to “Fundación Mango del Ecuador”, there are no food irradiation plants in Ecuador.

#### **3.1 SOURCE**

Fundacion Mango del Ecuador  
Ing. Johnny Jara  
Executive Director  
[jjara@mangoecuador.org](mailto:jjara@mangoecuador.org)  
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#### **3.2 USDA GUIDELINES RELATED TO IRRADIATED MANGOS FROM ECUADOR**

According to the USDA Fresh Fruits and Vegetables Import Manual (Attachment 2), irradiation as an optional treatment is available only after an exporting country has entered into a frame work equivalency work plan agreement and met other requirements as specified in 7CFR 305.2 (Appendix B). Currently, Ecuador has not entered into a work plan agreement.



## **4. GUATEMALA**

According to the “Asociacion Guatemalteca de Exportadores” (AGEXPORT), there are no Food Irradiation Plants in Guatemala.

### **4.1 SOURCE**

AGEXPORT  
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Comité de Mango/Berries  
15 Av. 14-72 Zona 13  
Guatemala C.A. 01013  
[Erick.lara@agexport.org.gt](mailto:Erick.lara@agexport.org.gt)  
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### **4.2 USDA GUIDELINES RELATED TO IRRADIATED MANGOS FROM GUATEMALA**

According to the USDA Fresh Fruits and Vegetables Import Manual (Attachment 2), irradiation as an optional treatment is available only after an exporting country has entered into a frame work equivalency work plan agreement and met other requirements as specified in 7CFR 305.2 (Appendix B). Currently, Guatemala has not entered into a work plan agreement. Fruits irradiated in the country of origin and accompanied by PPQ form 203 to confirm irradiation may enter any state. However, untreated fruits and vegetables, intended to be irradiated for quarantine pests, cannot be treated within nor transit through the following states: Alabama, Arizona, California, Florida, Georgia (except for treatment in Atlanta, GA), Kentucky, Louisiana, Mississippi (except for treatment in Gulfport, MS), Nevada, New Mexico, North Carolina (except for treatment in Wilmington, NC), South Carolina, Tennessee, Texas (except untreated products to be irradiated may transit through Dallas/Ft. Worth) and Virginia.

## **5. HAITI**

According to “Association Nationale des Exportateurs de Mangues” (ANEM), there are no Food Irradiation Plants in Haiti.



## 5.1 SOURCE

ANEM

Morose Charles

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## 5.2 USDA GUIDELINES RELATED TO IRRADIATED MANGOS FROM HAITI

According to the USDA Fresh Fruits and Vegetables Import Manual (Attachment 2), Irradiation as an optional treatment is available only after an exporting country has entered into a frame work equivalency work plan agreement and met other requirements as specified in 7CFR 305.2 (Appendix B). Currently Haiti has not entered into a work plan agreement.

## 6. INDIA

Currently in India only one plant is being used for irradiation processing of mango for export to the U.S. (KRUSAHK). It is estimated that by the end of 2009 another 2 more plants will be created to irradiate mangos.

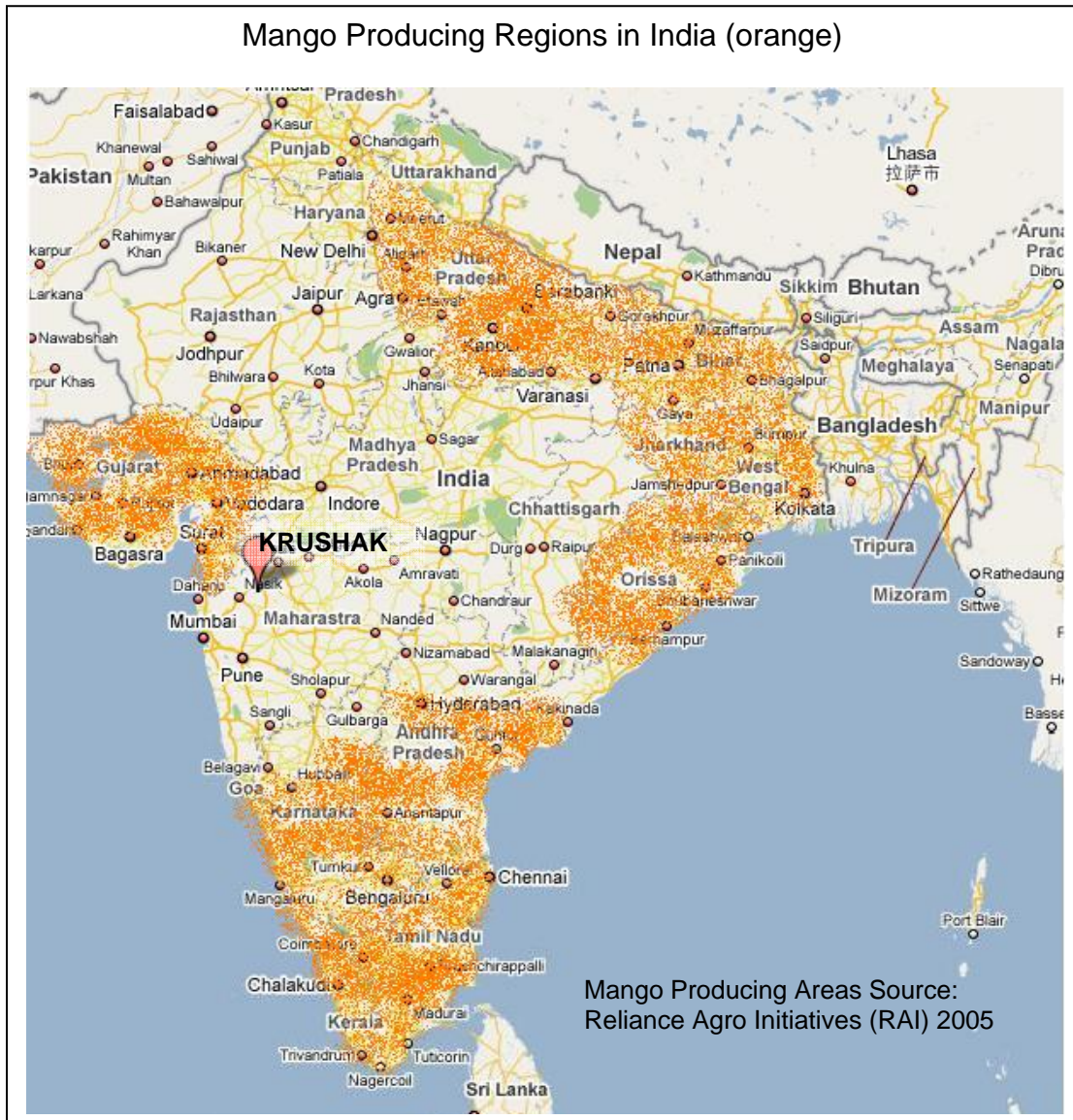
### 6.1 KRUSHAK (“Krushi Utpadan Sanrakshan Kendra” meaning Agro Produce Preservation Center)

This plant is owned by Bhabha Atomic Research Center (BARC), Mumbai. It was commissioned in 2002 and operated by the Food Technology Division (FTD) of BARC until 2007. For commercial operations and maintenance, under a Memorandum of Understanding, the operation of the KRUSHAK irradiation plant was handed over to the Board of Radiation & Isotope Technology (BRIT) in 2007. BRIT is a constituent commercial unit of the Department of Atomic Energy. In 2007, BRIT entered into a Public-Private partnership with a fruit exporting company, Desai Fruit & Vegetable Co., for commercial operations, mainly export of mangoes to US. The plant was approved by USDA – APHIS for quarantine treatment of mango in April 2007. Last year, 157 tons of mangos were processed at the HRUSKAH irradiation plant. This year the figure is approximately 250 tons of mangos. Maximum capacity information wasn't available. They have also carried out large scale trials for the purpose of technology demonstration and commercial irradiation of commodities including onions, potatoes, mangoes, cereal products and spices, in this facility. FTD –



BARC completed research during the 70's and 80's on extending the shelf-life of perishable products by delaying the ripening process on quarantine treatments; currently, they are working on two research projects in two universities on irradiation processing of mango (appendix A).

## 6.2 LOCATION





### **6.3 SOURCE**

BARC  
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Tel. +91 (22) 2550-5180  
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[www.barc.gov.in](http://www.barc.gov.in)

### **6.4 USDA GUIDELINES RELATED TO IRRADIATED MANGOS FROM INDIA**

According to the USDA Fresh Fruits and Vegetables Import Manual (Attachment 2), fruits from India must be pre-cleared and pretreated (irradiated) with T105-a-2 in India. The Pre-clearance Form 203 confirming irradiation must be presented at the time of entry. Consignments of mangos, irradiated as described in 7 CFR 305.31, must be accompanied by a phytosanitary certificate with two additional declarations stating that:

- “The mangoes were subjected to one of the pre- or post-harvest mitigation options described in 7 CFR 319.56-2tt (b)”
- “The mangoes were inspected during preclearance activities and found free of *Cytophthora mangiferae*, *Macrophoma magniferae* and *Xanthomonas cnpresstris* pv *mangiferae* indicae”

See special procedures for Pre-cleared Irradiated Fruits and Vegetables (Appendix C).



## 7. MEXICO

According to the “Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria “(SENASICA) office of the Mexican Agriculture Ministry that oversees animal and plant health and quality, there is one irradiation plant currently working (Sterigenics) in Hidalgo, Mexico, this plant hasn’t been certified by APHIS. A second plant is currently under construction (Benebion) in San Luis Potosi. A project for a third irradiation plant to be build is underway. At this time a definite location for a third irradiation plant has not been identified, but possibilities point to locating the plant in the Mexican state of Jalisco.

### 7.1 STERIGENICS

This plant located in Hidalgo is owned by Sterigenics International, Sterilization Company which has 40 service centers in 11 countries. This plant has been working for over eight years mainly processing dry chilies. The maximum capacity of this plant is **confidential**. Sterigenics is currently working to get APHIS certification to export irradiated fruits. Sterigenics plans to have this certification by September 2008. As part of their certification program they are looking to irradiate mangos and citrus.

### 7.2 BENEZION

This plant is owned by Phitosan S.A. de C.V., a private company that is currently run by Arved Deeke, CEO. This plant is still under construction and is scheduled to be complete by January 2009. This plant will have an annual capacity of 300,000 metric tons and will be using NORDION’s technology. In addition to mangos, this plant will be processing citrus, guavas, strawberries, raspberries, blueberries, spices, salt, apples, cranberries, cherries, peaches, prunes, dried products (garlic, onion, chilies, etc.), among others. The location of this plant is in Matehuala, San Luis Potosi, near one of the main roads that leads to the Texas/Mexico border.



### 7.3 LOCATION



### 7.4 SOURCES

SENASICA  
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## **7.5 USDA GUIDELINES RELATED TO IRRADIATES MANGOS FROM MEXICO**

There is no information related to irradiated mangos from Mexico in the Fresh Fruits and Vegetables Import Manual.



## **8. PERU**

According to the “Servicio Nacional de Sanidad Agraria” (SENASA), Office of the Peruvian Agricultural Ministry that oversees Plant Health in Peru, there is one irradiation plant working mainly with dry goods (PIMU), and there is a project between FrioAereo and NORDION for the development and construction of a second plant.

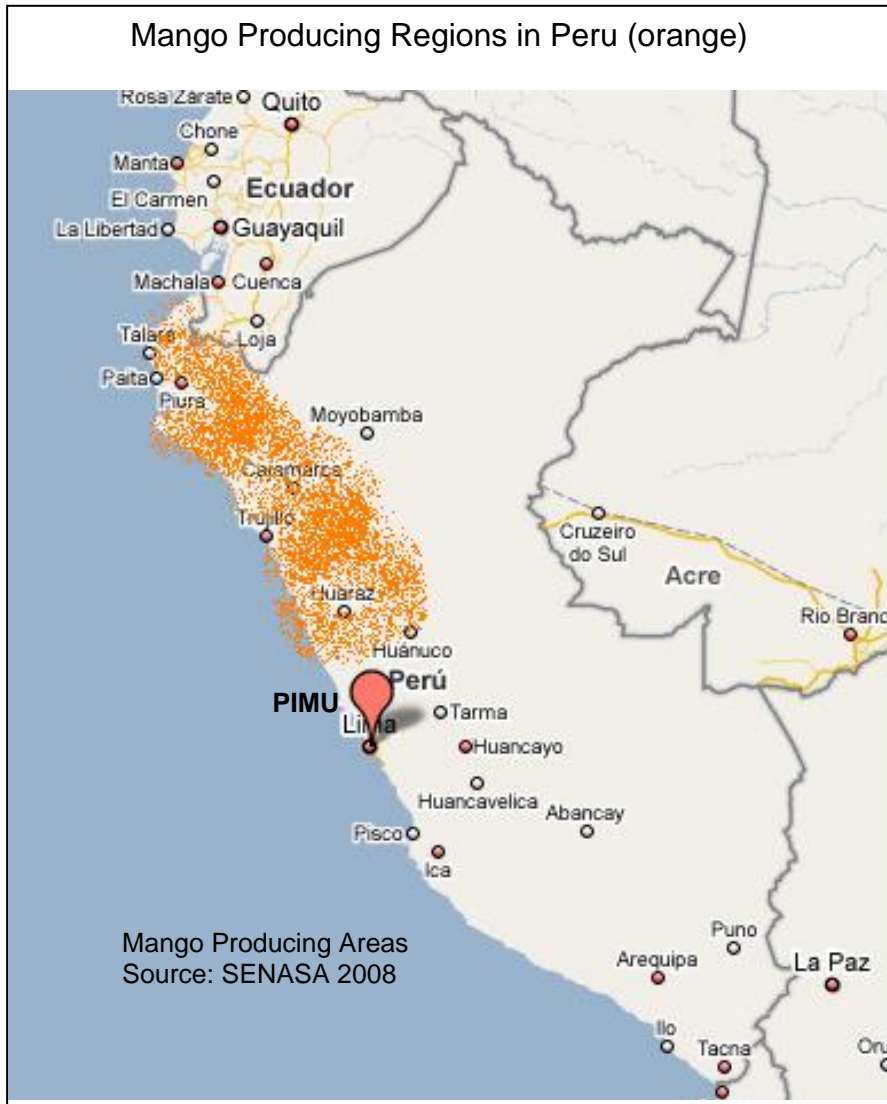
### **8.1 PIMU (Planta de Irradiacion Multiusos)**

This plant belongs to the “Instituto Peruano de Energia Nuclear” (IPEN), a governmental institution that has as its main objective the promotion, regulation and development of activities that utilize nuclear energy. This plant has a maximum capacity of 500,000 Curies (maximum capacity in volume wasn't available). PIMU mainly works with dry goods such as teas, medicinal herbs, organic colorings, spices, etc. This plant hasn't started working on fresh fruits, but they are open to exploring the fresh produce market if demand exists for their services.

### **8.2 FRIOAEREO**

This is a project being developed by FrioAereo, an association of growers and exporters of fresh produce from Peru, and NORDION. The project is owned by FrioAereo; as part of the development of the project FrioAereo is conducting research on acceptance of irradiated produce in the U.S. This research project will last for approximately 6 months, and the results would determine the viability of the project. The main products being considered in the project are asparagus, mangos, and citrus. This plant would be constructed in Lima, Peru.

### 8.3 LOCATION





## 8.4 SOURCES

APEM (Asociación Peruana de Productores y Exportadores de Mango)

Juan Carlos Rivera

Executive Director

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PIMU

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## **8.5 USDA GUIDELINES RELATED TO IRRADIATED MANGOS FROM PERU**

According to the Fresh Fruits and Vegetables Import Manual (Attachment 2), irradiation as an optional treatment is available only after an exporting country has entered into a framework equivalency work plan agreement and met other requirements as specified in 7CFR 305.2 (Appendix B). Currently, Peru has not entered into a work plan agreement. Fruits irradiated in the country of origin and accompanied by a PPQ Form 203 to confirm irradiation may enter any State. However, untreated mangos, intended to be irradiated for quarantine pests, cannot be treated within nor transit through the following states: Alabama, Arizona, California, Florida, Georgia (except for treatment in Atlanta, GA), Kentucky, Louisiana, Mississippi (except for treatment in Gulfport, MS), Nevada, New Mexico, North Carolina (except for treatment in Wilmington, NC), South Carolina, Tennessee, Texas (except untreated mangos to be irradiated may transit through Dallas/Ft. Worth) and Virginia.

## **9. PHILIPPINES**

There are 2 (two) irradiation plants in Philippines, the Cobalt-60 Multipurpose Irradiation Facility (MIF) and the Gammacell-220, both operated by the Philippine Nuclear Research Institute (PNRI), who extends nuclear and allied services to clients from industry.

### **9.1 MIF & GAMMACELL-220**

These facilities are used by various clients of PNRI, for food irradiation, medical products sterilization and for research purposes. The food/agricultural products being irradiated in the PNRI irradiation facilities are: spices/dehydrated products; fresh fruits (mangos, papayas, mungbean); grains (rice, corn); and bulbs (onion, garlic).



## 9.2 LOCATION



## 9.3 SOURCES

PNRI (Philippine Nuclear Research Institute)  
Common Wealth Ave., Diliman  
Quezon City, Philippines  
Tel. +63 2929-6011  
+63 2920-8789  
Fax +63 2920-1646  
[information@pnri.dost.gov.ph](mailto:information@pnri.dost.gov.ph)  
[www.pnri.dost.gov.ph](http://www.pnri.dost.gov.ph)



Republic of the Philippines Department of Agriculture  
Elliptical Road, Diliman,  
Quezon City, Philippines  
Tel. +63 2928-8741 to 65  
[webgroup@da.gov.ph](mailto:webgroup@da.gov.ph)  
[www.da.gov.ph](http://www.da.gov.ph)

Specific mango page:  
[http://www.da.gov.ph/wps/portal/!ut/p/kcxml/04\\_Sj9SPykssy0xPLMnMz0vM0Y\\_QjzKLN4g3NAoESYGYjvqRMJEgfW99X4\\_83FT9AP2C3lhyR0dFRQAXNd-N/delta/base64xml/L0IDU0IKQ1RPN29na21BISEvb0VvUUFBsvFnakZJQUFRaENFSVFqR0VBLzRKRmIDbzBlADfY29uUVZHaGQtc0IRIS83XzBfMUxTLzU5MjA!/?WCM\\_PORTLET=PC\\_7\\_0\\_1LS\\_WCM&WCM\\_GLOBAL\\_CONTEXT=/wps/wcm/connect/Subj2\\_Agribiz/Philippine+Agribusiness/Commodity+Profile%7CFact+Sheet%7CRoad+Map/Mango](http://www.da.gov.ph/wps/portal/!ut/p/kcxml/04_Sj9SPykssy0xPLMnMz0vM0Y_QjzKLN4g3NAoESYGYjvqRMJEgfW99X4_83FT9AP2C3lhyR0dFRQAXNd-N/delta/base64xml/L0IDU0IKQ1RPN29na21BISEvb0VvUUFBsvFnakZJQUFRaENFSVFqR0VBLzRKRmIDbzBlADfY29uUVZHaGQtc0IRIS83XzBfMUxTLzU5MjA!/?WCM_PORTLET=PC_7_0_1LS_WCM&WCM_GLOBAL_CONTEXT=/wps/wcm/connect/Subj2_Agribiz/Philippine+Agribusiness/Commodity+Profile%7CFact+Sheet%7CRoad+Map/Mango)

## 10. USDA GUIDELINES RELATED TO IRRADIATED MANGOS FROM PHILIPPINES

According to the Fresh Fruits and Vegetables Import Manual (Attachment 2), requirements for commercial consignments of mangoes from **Guimaras Islands** into all of the US are:

- The consignment must be accompanied by a PPQ Form 203 signed by the APHIS inspector on site in the Philippines to validate foreign site preclearance. Boxes must be marked as "Vapor heat treated under USDA-APHIS Supervision"
- Consignments must be accompanied by a phytosanitary certificate issued by the Republic of the Philippines Department of Agriculture containing two additional declarations: "The mangoes have been treated for fruit flies of the genus *Bactrocera* in accordance with 7 CFR 319.56.2ii(b)", and, "The mangoes were grown on the island of Guimarras".

Requirements for commercial consignments of mangoes from **other than Guimaras Island** (except Palawan) entering Guam or Hawaii **only**:

- The consignment must be accompanied by a PPQ Form 203 signed by the APHIS inspector on site in the Philippines to validate foreign site preclearance. Boxes must be marked as Vapor heat treated under USDA-APHIS Supervision.
- Consignments must be accompanied by a phytosanitary certificate issued by the Republic of the Philippines Department of Agriculture and contain an additional declaration, "Them angoes have been treated for fruit flies of the genus *Bactrocera* in accordance with 7 CFR 319.56.2ii (b)."



- Boxes must be marked, "For Distribution in Guam and Hawaii Only." Mangoes from Palawan are **prohibited** entry.

## **11. USDA GUIDELINES FOR CERTIFYING IRRADIATION TREATMENT FACILITIES (See Attachment 1 for complete document)**

In order to receive authorization to conduct approved phytosanitary irradiation treatments, an irradiation facility must obtain PPQ Form 482, a Certificate of Approval from the USDA-APHIS-PPQ Treatment Quality Assurance Unit (TQAU).

### **CERTIFICATION REQUIREMENTS**

The facility must be certified by the national nuclear regulatory authority of the country where the facility is located prior to involvement from USDA.

In order to receive a Certificate of Approval for treating commodities to mitigate regulated pests, a facility must complete the following in numerical order:

- 11.1.1 Operational Workplan (OWP): An Operational Workplan (OWP) must be established prior to a Cooperative Agreement. The OWP provides general guidelines for safeguarding procedures.
- 11.1.2 Addenda to the Workplan: the addenda to the OWP identifies specific information not covered in the OWP, such as the commodity(ies) and pest(s) that will be irradiated and details pertinent to facility operation.
- 11.1.3 Cooperative Agreement: The Cooperative Agreement establishes a trust fund between the importing and exporting countries.
- 11.1.4 Plan Approval Application: The Plan Approval Application must be completed in its entirety and submitted to:  
*USDA-APHIS-PPQ-CPHST  
Treatment Quality Assurance Unit  
1730 Varsity Drive  
Raleigh, NC 27606-5202  
Phone: 919-855-7450.*
- 11.1.5 On-site certification: When all documents have been approved, an official on-site visit will be scheduled. During this visit, the certifying official will verify the accuracy of the information submitted in the Plan Approval Application, review the Standard Operating Procedures (SOP), inspect the dosimetry equipment and verify that the personnel are proficient in its use. The on-site certification will



also include inspection of the segregation structures to ensure misidentification or cross-contamination of treated and untreated commodities does not occur. Phytosanitary measures must be in place to guard against pest infestation from the perimeter of the facility. The certifying official will also review the dose mapping procedures and records and verify that data management procedures are acceptable.

- 11.1.6 Compliance Agreement: The Compliance Agreement serves as the legal notice to the treatment facility to follow the OWP. The Compliance Agreement defines what the facility must do before, during and after receipt of the fruit and any additional requirements specific to the facility.

## RECERTIFICATION

Recertification will be conducted when at least one of the major non-compliance issues described below have been detected:

- A problem with the treatment process has been identified by APHIS or the NPOO.
- Change in management which substantially affects any aspect of the treatment process.
- Operational or structural changes of the facility.
- Replenishment, rearrangement or change of the radiation-producing source

**IMPORTANT:** Annual recertification is NOT necessary.

## AUDITS

Audits will be performed at the discretion of the Director of APHIS-PPQ-CPHST-TQAU. On –site audits will include review of the dosimetry, dose mapping, safeguarding measures, record keeping, and the treatment process and system integrity as a whole.

Electronic audits will also be performed by TQAU to review routine dosimetry data and dose mapping data.



## **CERTIFICATE OF APPROVAL**

Upon facility approval, the USDA will issue a PPQ Form 482, Certificate of Approval, outlining the terms, conditions, and restrictions of the approval. The USDA approval status of all irradiation treatment facilities, both domestic and foreign, treating commodities to mitigate regulated agricultural pests will be tracked by USDA-APHIS-PPQ=CPHST-TQAU.

The Certificate of Approval can be revoked if major non-compliance issues are detected.



## APPENDIX A

### Research Work Done on Food Irradiation:

1. Bhushan, B., Kadam, R.M., Thomas, P., Singh, B.B. (1995) Evaluation of electron spin resonance technique for the detection of irradiated mango (*Mangifera indica*) fruit, *Int. J. Food. Sci. & Technol.* 29, 679-686.
2. Thomas, P., Bhushan, B., Joshi, M.R., Ramamurthy, M.S. (1993) Comparative studies on the efficacy of gamma irradiation, heat, refrigeration and combined treatment for mango fruit, Final Research Co-ordination Meeting of the Asian Regional Co-operation Project on Food Irradiation with Emphasis on Process Control and Acceptance in Asia; Taejon (KR); 20-25 Sep 1993, IAEA-TECDOC—871, p. 299-314
3. Thomas, P. (1986) Radiation preservation of foods of plant origin. Part-III. Tropical fruits: Banana, mangoes and papayas. *CRC Critical Reviews in Food Science & Nutrition*, 23, 147-205.
4. Gholap, A.S., Bandyopadhyay, C. and Nadkarni, G.B. (1986) Aroma development in mango fruit. *J. Food Biochem.*, 10:3, 217–229.
5. Gholap, A.S., and Bandyopadhyay, C. (1984) Characterization of Mango-like aroma in *Curcuma Amada* Roxb. *J. Agric. Food Chem.* 32: 57-59.
6. Gholap, A.S., and Bandyopadhyay, C. (1980) Fatty acid biogenesis in ripening mango (*Mangifera indica* L. var Alphonso), *J. Agric. Food Chem.*, 28, 839-841.
7. Gholap, A.S., and Bandyopadhyay, C. (1977) Characteristics of green aroma of raw mango (*Mangifera indica* L.) *J. Agric. Food Chem.*, 31, 796–801.
8. Ranagrajan, A.N., and Shrikhande, A.J. (1976) Mango peel waste as source of pectin, *Curr. Sc.*, 45, 620-621.
9. Thomas, P., Janave, M.T. (1975) Effects of gamma irradiation and storage temperature on carotenoids and ascorbic acid content of mangoes on ripening, *J. Sc. Fd. Agric*, 26, 1503-1512.
10. Gholap, A.S., and Bandyopadhyay, C. (1975) Comparative assessment of aromatic principles of ripe alphonso and langra mango, *J. Food Sci. & Technol.*, 12, 262-263.
11. Gholap, A.S., and Bandyopadhyay, C. (1975) Contribution of lipid to aroma of ripening mango (*Mangifera indica* L.), *JAOCS*, 52, 514-516.
12. Padwal-Desai, S.R., Ghanekar, A.S., Thomas, P., and Sreenivasan, A. (1973) Heat radiation combination for control of mould infestation in harvested fruits and processed cereals foods. *Acta Alimentaria*, 2, 189-207.
13. Bandyopadhyay, C., and Gholap, A.S. (1973) Relationship of aroma and flavour characteristics of mango (*Mangifera indica* L.) to fatty acid composition, *J. Sci. fd., Agric.*, 24, 1497-1503.
14. Bandyopadhyay, C., Gholap, A.S., and Sreenivasan, A. (1973) Studies on aroma of ripe mango pulp: Isolation and Concentration of the aroma, *Ind. J. of Technol.* 11, 275-277.
15. Dharkar, S.D., Sreenivasan, A. (1972) Irradiation As A Method For Improved Storage And Transportation Of Mangoes, *ISHS Symposium on mango and Mango Culture*, *ISHS, Acta Hort.* 24:259-259.
16. Dharkar, S.D, Sreenivasan A., and Thomas P. (1970) Physiological effects of gamma radiation on some tropical fruits: Disinfestation of fruit by irradiation: Proceedings of a Panel, Honolulu, Hawaii, USA, 7-11 Dec 1970. P. 65-91.
17. Dharkar, S.D., Savagaon, K.A., Srirangarajan, A.N., Sreenivasan, A. (1966) Irradiation of Mangoes. II. Radiation effects on skin-coated Alphonso mangoes *J Food Sci.* 31, 870–877.



18. Dharkar, S. D., Savagaon, K. A., Srirangarajan, A. N., and Sreenivasan, A. (1966). Irradiation of Mangoes. I. Radiation-induced delay in ripening of Alphonso mangoes. J. Food Sci., 31, 863- 869
19. Dharkar, S. D., Savagaon, K. A., Kumta, U. S., Sreenivasan, A. (1966) Development of a radiation process for some Indian fruits: Mangoes and Sapodillas. J. Food Sci., 31, 22-28.
20. Dharkar, S.D. and Sreenivasan, A. (1966) Irradiation of tropical fruits and vegetables, International Symposium On Food Irradiation; Karlsruhe (Germany, F.R.); 6 - 10 Jun 1966, IAEA; Vienna; 1966, P. 635-651.



## APPENDIX B

### Part 305.2 Irradiation treatment of imported plant pests.

Authority: 7 U.S.C. 7701-7772; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

#### Sec. 305.1 Definitions.

The following definitions apply for the purposes of this part:

**Administrator.** The Administrator, Animal and Plant Health Inspection Service, United States Department of Agriculture, or any person delegated to act for the Administrator in matters affecting this part.

**APHIS.** The Animal and Plant Health Inspection Service, United States Department of Agriculture.

**Dose mapping.** Measurement of absorbed-dose within a process load using dosimeters placed at specified locations to produce a one-, two-, or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

**Dosimeter.** A device that, when irradiated, exhibits a quantifiable change in some property of the device that can be related to absorbed dose in a given material using appropriate analytical instrumentation and techniques.

**Dosimetry system.** A system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

**Inspector.** Any employee of the Animal and Plant Health Inspection Service or other person authorized by the Administrator to inspect and certify the plant health status of plants and products under this part.

#### Sec. 305.2 Irradiation treatment of imported fruits and vegetables for certain fruit flies and mango seed weevils.

(a) Approved doses. Irradiation at the following doses for the specified plant pests, carried out in accordance with the provisions of this section, is approved as a treatment for all regulated articles (i.e., fruits, vegetables, cut flowers, and foliage):

TABLE 3-4 IRRADIATION FOR CERTAIN PLANT PESTS IN IMPORTED REGULATED ARTICLES<sup>1</sup>

Scientific Name	Common Name	Dose (gray)
<i>Anastrepha ludens</i>	Mexican fruit fly	70
<i>Anastrepha obliqua</i>	West Indian fruit fly	70
<i>Anastrepha serpentina</i>	Sapote fruit fly	100
<i>Anastrepha suspensa</i>	Caribbean fruit fly	70
<i>Bactrocera jarvisi</i>	Jarvis fruit fly	100
<i>Bactrocera tryoni</i>	Queensland fruit fly	100
<i>Brevipalpus chilensis</i>	False red spider mite	300
<i>Conotrachelus nenuphar</i>	Plum curculio	92



<i>Crotophlebia ombrodelta</i>	Litchi fruit moth	250
<i>Crotophlebia illepada</i>	Koa seedworm	250
<i>Cylas formicarius elegantulus</i>	Sweetpotato weevil	150
<i>Cydia pomonella</i>	Codling moth	200
<i>Eusecepes postfasciatus</i>	West Indian sweetpotato weevil	150
<i>Grapholita molesta</i>	Oriental fruit moth	200
<i>Omphisa anastomosalis</i>	Sweetpotato vine borer	150
<i>Rhagoletis pomonella</i>	Apple maggot	60
<i>Sternochetus mangiferae (Fabricus)</i>	Mango seed weevil	300
Fruit flies of the family <i>Tephritidae</i> not listed above		150
Plant pests of the class <i>Insecta</i> not listed above, except pupae and adults of the order Lepidoptera		400

1 There is a possibility that some cut flowers could be damaged by such irradiation. See paragraph (n) of this section.

- (b) Location of facilities. Where certified irradiation facilities are available, an approved irradiation treatment may be conducted for any fruit or vegetable either prior to consignment to the United States or in the United States. Irradiation facilities certified under this section may be located in any State on the mainland United States except Alabama, Arizona, California, Florida, Georgia<sup>1</sup>, Kentucky, Louisiana, Mississippi<sup>1</sup>, Nevada, New Mexico, North Carolina<sup>1</sup>, South Carolina, Tennessee, Texas, and Virginia. Prior to treatment, the articles to be irradiated may not move into or through any of the States listed in this paragraph, except that movement is allowed through Dallas/Fort Worth, Texas, as an authorized stop for air cargo, or as a transloading location for consignments that arrive by air but that are subsequently transloaded into trucks for overland movement from Dallas/Fort Worth into an authorized State by the shortest route.
- (c) Compliance agreement with importers and facility operators for Irradiation in the United States. If irradiation is conducted in the United States, both the importer and the operator of the irradiation facility must sign compliance agreements with the Administrator. In the facility compliance agreement, the facility operator must agree to comply with any additional requirements found necessary by the Administrator to prevent the escape, prior to irradiation, of any fruit flies that may be associated with the articles to be irradiated. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by the Administrator to ensure the consignment is not diverted to a destination other than treatment and to prevent escape of plant pests from the articles to be irradiated during their transit from the port of first arrival to the irradiation facility in the United States.
- (d) Compliance agreement with irradiation facilities outside the United States. If irradiation is conducted outside the United States, the operator of the irradiation facility must sign a compliance agreement with the Administrator and the plant protection service of the country in which the facility is located. In this agreement, the facility operator must agree to comply

<sup>1</sup> Irradiation facilities may be located at the maritime ports of Gulfport, MS, or Wilmington, NC, or the airport of Atlanta, GA, if the following special conditions are met: The articles to be irradiated must be imported packaged in accordance with paragraph (g)(2)(i)(A) of this section; the irradiation facility and APHIS must agree in advance on the route by which consignments are allowed to move between the vessel on which they arrive and the irradiation facility; untreated articles may not be removed from their packaging prior to treatment under any circumstances; blacklight or sticky paper must be used within the irradiation facility, and other trapping methods, including Jackson/methyl eugenol and McPhail traps, must be used within the 4 square miles surrounding the facility; and the facility must have contingency plans, approved by APHIS, for safely destroying or disposing of fruit.



with the requirements of this section, and the plant protection service of the country in which the facility is located must agree to monitor that compliance and to inform the Administrator of any noncompliance.

- (e) Certified facility. The irradiation treatment facility must be certified by the Administrator. Recertification is required in the event of an increase or decrease in the amount of radioisotope, 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. In order to be certified, a facility must:
  - (1) Be capable of administering the minimum absorbed ionizing radiation doses specified in paragraph (a) of this section to the articles<sup>2</sup>;
  - (2) Be constructed so as to provide physically separate locations for treated and untreated articles, except that articles traveling by conveyor directly into the irradiation chamber may pass through an area that would otherwise be separated. The locations must be separated by a permanent physical barrier such as a wall or chain link fence 6 or more feet high to prevent transfer of cartons, or some other means approved during certification to prevent reinfestation of articles and spread of pests;
  - (3) If the facility is located in the United States, the facility will only be certified if the Administrator determines that regulated articles will be safely transported to the facility from the port of arrival without significant risk that plant pests will escape in transit or while the regulated articles are at the facility.
- (f) Monitoring and interagency agreements. 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. Facilities that carry out irradiation [[Page 65028]] 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 work plan. To ensure the appropriate level of monitoring, before articles may be imported in accordance with this section, the following agreements must be signed:
  - (1) Irradiation treatment framework equivalency work plan. The plant protection service of a country from which articles are to be imported into the United States in accordance with this section must sign a framework equivalency work plan with APHIS. In this plan, both the foreign plant protection service and APHIS will specify the following items for their respective countries:
    - (i) Citations for any requirements that apply to the importation of irradiated articles;
    - (ii) The type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated articles into that country; and
    - (iii) Any other conditions that must be met to allow the importation of irradiated articles into that country.

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<sup>2</sup> The maximum absorbed ionizing radiation dose and the irradiation of food is regulated by the Food and Drug Administration under 21 CFR part 179.



- (2) Facility preclearance work plan. Prior to commencing importation into the United States of articles treated at a foreign irradiation facility, APHIS and the plant protection service of the country from which articles are to be imported must jointly develop a preclearance work plan that details the activities that APHIS and the foreign plant protection service 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 work plan 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 work plan will be reviewed and renewed by APHIS and the foreign plant protection service on an annual basis.
  - (3) Trust fund agreement. Irradiated articles may be imported into the United States in accordance with this section only if the plant protection service of the country in which the irradiation facility is located has entered into a trust fund agreement with APHIS. That agreement requires the plant protection service 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 plant protection service 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 plant protection service 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 plant protection service or held on account until needed, at the option of the plant protection service.
- (g) Packaging. Articles that are irradiated in accordance with this section must be packaged in cartons in the following manner:
- (1) All articles treated with irradiation must be shipped in the same cartons in which they are treated. Irradiated articles may not be packaged for consignment in a carton with non irradiated articles.
  - (2) For all articles to be irradiated upon arrival in the United States, the articles must be packed in cartons that have no openings that will allow the entry of fruit flies and that are sealed with seals that will visually indicate if the cartons have been opened. They may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the fruit in the carton.
  - (3) For all articles irradiated prior to arrival in the United States:



- (i) The articles to be irradiated must be packaged either:
  - (A) In insect-proof cartons that have no openings that will allow the entry of fruit flies. 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 the entry of fruit flies and prevents oviposition by fruit flies into the articles in the carton<sup>3</sup>;
  - (B) In non insect-proof-proof cartons that are stored immediately after irradiation in a room completely enclosed by walls or screening that completely precludes access by fruit flies. If stored in non insect-proof-proof cartons in a room that precludes access by fruit flies, prior to leaving the room each pallet of cartons must be completely enclosed in polyethylene, shrink-wrap, or another solid or netting covering that completely precludes access to the cartons by fruit flies.
- (ii) To preserve the identity of treated lots, each pallet-load of cartons containing the articles must be wrapped before leaving the irradiation facility in one of the following ways:
  - (A) With polyethylene shrink wrap;
  - (B) With net wrapping; or
  - (C) With strapping so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap.
- (iii) Packaging must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment. 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 must have the required label information on each individual carton.
- (h) Dosimetry systems at the irradiation facility.
  - (1) Dosimetry mapping must indicate the doses needed to ensure that all the commodity will receive the minimum dose prescribed.
  - (2) Absorbed dose must be measured using an accurate dosimetry system that ensures that the absorbed dose meets or exceeds the absorbed dose required by paragraph (a) of this section (150, 210, 225, 250, or 300 gray, depending on the target species of fruit fly or seed weevil).
  - (3) When designing the facility's dosimetry system and procedures for its operation, the facility operator must address guidance and principles from American Society for Testing and Materials (ASTM) standards<sup>4</sup> or an [[Page 65029]] equivalent standard recognized by the Administrator.
- (i) Records. 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

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<sup>3</sup> If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Science and Technology, 1730 Varsity Drive, Suite 400 Raleigh, NC 27606.



compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

- (j) Request for certification and inspection of facility. Persons requesting 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, Oxford Plant Protection Center, 901 Hillsboro Street, Oxford, NC 27565. 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.
- (k) Denial and withdrawal of certification.
  - (1) 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.
- (l) Department not responsible for damage. This treatment is approved to assure quarantine security against the listed fruit flies. From the literature available, the fruits and vegetables authorized for treatment under this section are believed tolerant to the treatment; however, the facility operator and shipper are responsible for determination of tolerance. The Department of Agriculture and its inspectors assume no responsibility for any loss or damage resulting from any treatment prescribed or monitored. Additionally, the Nuclear Regulatory Commission is responsible for ensuring that irradiation facilities are constructed and operated in a safe manner. Further, the Food and Drug Administration is responsible for ensuring that irradiated foods are safe and wholesome for human consumption. (Approved by the Office of Management and Budget under control number 0579-0155)



## APPENDIX C

### Precleared Irradiated Fruits and Vegetables Background

Food irradiation technology has been available and in use for over 30 years. Irradiation has been used to treat a variety of dry and fresh food products worldwide. The Food and Drug Administration (FDA) has approved irradiation as safe for foods. Varying doses of irradiation will either kill pests or, in the case of arthropod pests, kill or sterilize them.

#### **IMPORTANT:**

The dose of irradiation used to treat fruits and vegetables is not intended to kill quarantine plant pests, although it may be a result of the treatment. The irradiation dose is meant to be sufficient to prevent adult emergence, retard insect growth and development, or cause sterilization of the insect. It is therefore possible that live insects may be found after treatment; however, any pest risk will be mitigated.

Irradiation doses are authorized for approved fruits, vegetables, and herbs. Approved commodities are exposed to irradiation in the boxes in which they are packed. A list of target quarantine pests and approved irradiation doses can be found in the T105 Treatment Schedules in the *Treatment Manual* ([http://www.aphis.usda.gov/ppq/manuals/port/pdf\\_files/Treatment\\_Chapters/05-02-T100-5.pdf](http://www.aphis.usda.gov/ppq/manuals/port/pdf_files/Treatment_Chapters/05-02-T100-5.pdf)).

### APHIS Preclearance Process in Country of Origin

Fruits and vegetables are inspected for the presence of pests by an APHIS officer in the country of origin. The commodities are then authorized to be irradiated at a treatment facility. USDA-APHIS-CPHST or their designees certify irradiation facilities in foreign countries. Requirements for facility certification can be found in the *Treatment Manual*, Chapter 6, [http://www.aphis.usda.gov/ppq/manuals/port/pdf\\_files/Treatment\\_Chapters/06-08-CertifyingFacilities-6.pdf](http://www.aphis.usda.gov/ppq/manuals/port/pdf_files/Treatment_Chapters/06-08-CertifyingFacilities-6.pdf)

APHIS approved irradiation treatments are conducted **prior to** shipment to the United States. The treated articles are safeguarded immediately after the treatment is completed, until they reach the port of exit. Articles arrive in the United States with appropriate documentation. Importers must have an Import Permit from APHIS PPQ for the importation of such treated articles.

### Procedure at Ports of Entry

Use the following procedures for clearing articles treated by irradiation, entering under the APHIS Preclearance Program:

#### Step 1: Review Supporting Documentation.

- ❖ PPQ Form 203 (Foreign Site Certificate of Inspection) signed by APHIS officer at origin
- ❖ Phytosanitary Certificate (PC) issued by foreign government's National Plant Protection Organization (NPPO)
- ❖ APHIS Import Permit for this treatment or commodity complex (paper copy or e-permit)

If any required documents are lacking, HOLD the shipment and CONTACT the Field Office Agricultural Operational Specialist with details of missing documentation. If the documents are present as required, proceed to [Step 2](#).



**Step 2: Verify that the Entry Requirements in the *Fruits and Vegetables Manual* have been met**  
 If the entry requirements are **not** met, PROHIBIT ENTRY to the shipment. If the requirements are met, proceed to [Step 3](#).

**Step 3: Compare the PPQ Form 203 and the Phytosanitary Certificate (PC) with the Invoices and Other Import Documents**

- ❖ Make sure the container numbers (if applicable) agree.
- ❖ Verify that the PC is for the arriving shipment.
- ❖ Ensure that any required Additional Declarations are present and that the Treatment Block on the PC indicates the articles were treated with Irradiation.

<b>If the paperwork is:</b>	<b>Then:</b>
In order	RELEASE the shipment without further examination <sup>4</sup>
<b>Not</b> in order	CONTINUE TO Step 4 to conduct an integrity inspection

**Step 4: Conduct an Integrity Inspection**

Proceed with a cursory inspection of the container(s) and shipment. Look for tampering and verify that the following conditions are satisfied:

- ❖ That the fruits are packed in insect proof boxes or cartons with evidence of trace-back numbers
- ❖ That the cartons are labeled, marked or stamped with the words “Treated by Irradiation” or “Treated with Radiation” and display the International Radura Symbol:



- ❖ For sea shipments: That the palletized cartons are wrapped with polyethylene shrink wrap, net wrapping, or strapping (for the purpose of maintaining shipment integrity)
- ❖ For air shipments: If the cargo is solely on pallets, then each pallet must be wrapped with polyethylene shrink wrap, net wrapping, or strapping. However, if the cargo is containerized<sup>5</sup> polyethylene shrink wrap, net wrapping, or strapping is **not** required.

<sup>4</sup> Physical inspection will not be required as these articles are precleared by APHIS inspectors in the originating country. If the paperwork is not in order, contact the Ag Liaison or APL headquarters with details of any problems

<sup>5</sup> Shipment integrity is maintained by the container itself since they are loaded and sealed by the APHIS Preclearance officer immediately after treatment



## Step 5: Look for Pests Inside of the Container

If:	And there is:	Then:
Hitchhiking pests are found in the container <sup>1</sup>	→	1. HOLD shipment, and 2. SEND the interception for identification, see Appendix 1 (PPQ Form 309A) and Appendix 18 (Interceptions) of the <i>Manual for Agricultural Clearance</i>
No hitchhiking pests are found in the container	Evidence of tampering	CONTINUE to <a href="#">Step 6</a>
	No evidence of tampering	RELEASE the shipment

<sup>1</sup> Hitchhikers would not have been subject to irradiation. The PPQ Form 309 or 309A must clearly indicate the hitch-hiker pest was found “At Large.” Write the words “At Large” in parenthesis in the INSPECTED HOST block of the PPQ Form 309 or 309A.

### Step 6: Inspect the Commodity Where There Was Evidence of Tampering.

Hitchhikers found inside the boxes or cartons, and pests and diseases found associated with the commodity, would have been irradiated<sup>6</sup> since the fruits are irradiated inside the boxes or cartons. Submission of interception paperwork from these articles requires specialized handling to highlight their irradiated nature. If you intercept a pest, submit it and the completed PPQ Form 309 to the appropriate identifier. Include a photocopy of both the PPQ Form 203 and phytosanitary Certificate along the PPQ Form 309.

Ensure the following is written on the PPQ Form 309 or 309A:

- ❖ Write the words “irradiated article” or “treated by irradiation” either in the Remarks section, or in the case of the 309A, in the User Defined Field 1 (UDF1) block.
- ❖ If the pest intercepted was found inside the box, circle the word “WITH” in the HOST block of the 309, or in the PEST PROXIMITY field in the case of the 309A.
- ❖ If the pest was found associated with the article, circle either the word “IN” or “ON” respectively, in the HOST block of the 309, or in the PEST PROXIMITY field in the case of the 309A.

Include the unique Treatment Identification Number (TIN) as printed on the PPQ Form 203 in the Remarks section.

Treatment information is critical in order for the identifier to determine the actionable status of the interception. Contact the identifier to let them know of the forwarded pest, and also inform through the chain of command, the DFO Agricultural Operations Specialist, who will in turn notify the Agriculture Programs and Liaison (APL) Headquarters contact, Bruce Lewke.

### Step 7: Inspect for Contaminants.

Look for contaminants found associated with the container, the conveyance, inside the boxes, or associated with the articles Ports of Entry U.S. Customs and Border Protection, CBP personnel reserve the right to decide what action to take regarding the status of shipments found with extraneous contaminants (such as soil or grasses) found with the shipment of irradiated articles. These decisions are based on the regulations governing the contaminant.

<sup>6</sup> Recall that pest mortality is not the objective of irradiation treatments. Irradiation doses are set at a level sufficient to prevent adult emergence, retard insect growth and development, and/or cause insect sterilization.



In the case of botanical interceptions (such as seeds or suspected Federal Noxious Weeds) found either in the container or inside the boxes with the irradiated articles, forward these interceptions as urgents. Remedial action guidance will be provided by USDA.

#### Future Tool

An Irradiation Tracking Database will be available to verify the validity of the PPQ Form 203, but it will not be online until mid year 2007. If you have any doubt as to the validity of the documents, please contact the Field Office Agricultural Operational Specialist through the chain of command.