Introduction to Phytosanitary Irradiation

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- Irradiation History
- Definitions and Concepts
- ISPM 18
- ISPM 28

Phytosanitary Irradiation

- 1986. US FDA approves irradiation of fruits and vegetables for insect disinfestation
- 1989. Approval of Hawaii papaya; 1st rule phytosanitary irradiation treatment
- 1995. Hawaii produce exported with special permit
- 1996. USDA APHIS approves phytosanitary irradiation against fruit flies on any commodity

Phytosanitary Irradiation

2002. Irradiation approved for all admissible fruits and vegetables from all countries to US
2004. Australian mangos to New Zealand
2006. USDA APHIS approves generic doses
2007. Thai mango to United States
2011. First Port of Entry Irradiation Treatment
2012. Southern State Rule

Definitions & Concepts

Irradiation- The exposure of a substance to ionizing energy (radiation) for the purpose of achieving some desired technical benefit

Dose vs Absorbed Dose- Dose refers to the amount of ionizing radiation delivered; Absorbed dose refers to the quantity of radiating energy (in gray) absorbed per unit of mass of a specified target

Gray (Gy)- a unit of absorbed dose where 1 Gy is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg)

Phytosanitary Irradiation

Desired Outcomes:

- Mortality
- Sterilization
- Inactivity or devitalization
- Inability to emerge or fly

Since mortality is usually not the target response for irradiation, live insects may remain after treatment

IPPC

International Plant Protection Convention (IPPC) is multilateral treaty for international cooperation in plant protection

The IPPC is a global instrument for the harmonization of phytosanitary measures

The Commission on Phytosanitary Measures (CPM) is the governing body of the IPPC

ISPM

International Standards for Phytosanitary Measures (ISPMs) are adopted by the CPM

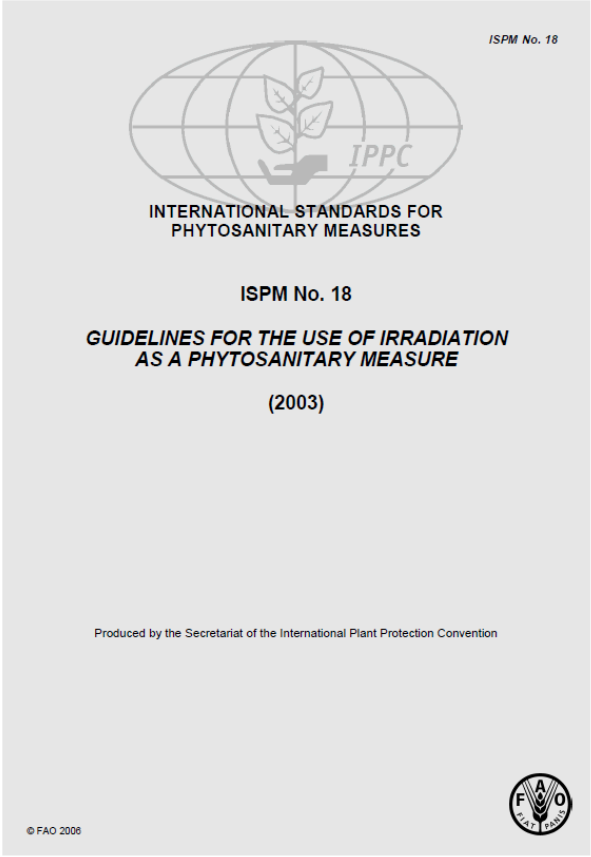
ISPMs are guidelines and recommendations concerning many aspects of plant health

List of all ISPMs is available at https://www.ippc.int

ISPM 18

ISPM 18: Guidelines for the use of irradiation as a phytosanitary measure

This standard provides technical guidance on procedures for the application of ionizing radiation as a phytosanitary treatment for regulated pests or articles



ISPM 18

This does not include treatments used for:

- Production of sterile organisms for pest control (SIT)
- Sanitary treatments (food safety or animal health)
- Preservation or improvement of commodity quality
- Inducing mutagenesis

ISPM 18-Guidelines

- Authority
- Treatment Objective
- Treatment
- Dosimetry
- Approval of Facilities
- Phytosanitary System Integrity
- Documentation by the Treatment Facility
- Inspection and Phytosanitary Certification by the NPPO
- Research

ISPM 18- Authority

The NPPO is responsible for the phytosanitary aspects of evaluation, adoption, and use of irradiation as a phytosanitary measure

Additionally, it is the NPPO responsibility to cooperate with other regulatory agencies and to avoid overlapping, conflicting, inconsistent, or unjustified requirements

ISPM 18- Treatment Objective

The objective of using irradiation as a phytosanitary measure is to prevent the introduction and spread of plant pests

This can be realized by achieving certain responses in the target pest(s) such as:

- mortality
- preventing development
- sterility
- inactivation

ISPM 18-Treatment

Ionizing radiation may be provided by:

- Radioactive isotopes (gamma rays from Co60 or Cs137)
- Electrons generated from machine sources (up to 10 MeV)
- X-rays (up to 5 MeV)

The unit of measurement for absorbed dose is the Gray (Gy)

Source Types

Gamma: Cobalt 60 or Cesium 137 emits photons during decay

E-beam: High energy electrons propelled (particle beam) from an electron gun

X-ray: High energy electrons are converted to X-rays (photons)

ISPM 18- Treatment

When implementing treatments, the following variables should be considered:

- Dose rate
- Treatment time
- Temperature
- Humidity
- Ventilation
- Modified atmospheres

ISPM 18- Treatment

Irradiation can be applied:

- As an integral part of packing operations
- To bulk unpackaged commodities
- At centralized locations such as the port of embarkation

When feasible, treatment can also be applied:

- At the point of entry
- A designated location in a third country
- A designated location within the country of final destination

ISPM 18- Dosimetry

Dosimetry ensures that the required Dmin is delivered to all parts of the consignment

Additionally, dosimetry ensures that variations are accounted for

- Density and composition of the material treated
- Variations in shape and size
- Variations in orientation of the product (stacking, volume, and packaging)

ISPM 18- Dosimetry

All components of the dosimetry systems should be calibrated in accordance with international (or national) standards

Dose mapping studies should be conducted to characterize the dose distribution within irradiation chambers and commodity

Routine dosimetry is critical to monitor efficacy for every irradiation treatment

ISPM 18- Facility Approval

Treatment facilities should be approved by relevant nuclear regulatory authorities

Treatment facilities should be subject to approval (qualification, certification, accreditation) by the NPPO

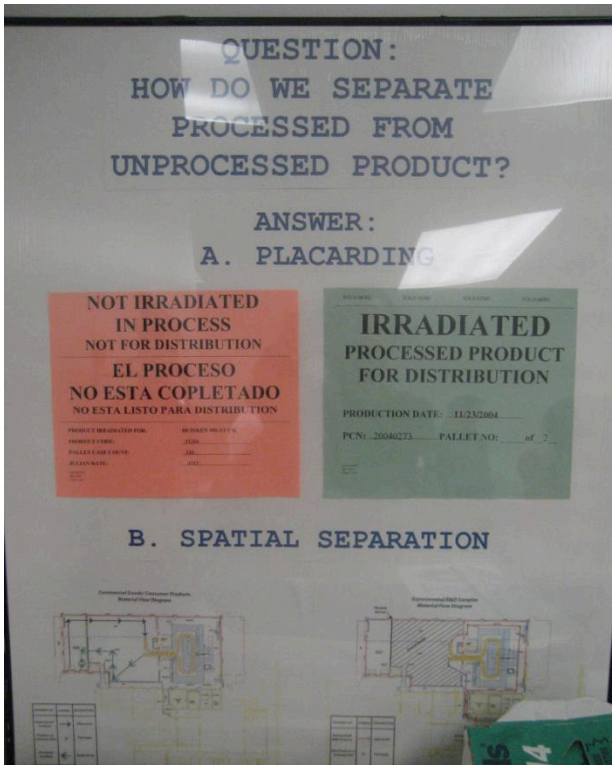
Phytosanitary re-approval should be conducted on a regular basis (as appropriate)

Dose mapping should be repeated following repairs, modifications, or adjustments in equipment or processes

ISPM 18- PI System Integrity

Confidence is based on assurance that the treatment is effective against the pest of concern and that the commodity has been adequately safeguarded

Treated commodities should be adequately segregated, clearly identified, and handled under conditions that will safeguard against re-infestation, or misidentification



ISPM 18- PI System Integrity

Packages should be labeled with treatment lot numbers and other identifying features allowing the identification of treatment lots and trace-back (i.e. packing and treatment facility identification and location, dates of packing and treatment).

ISPM 18- Documentation by Facility

Documentation of procedures (SOPs)

- Consignment handling procedures
- Orientation and configuration of the commodity
- Critical process parameters and monitoring
- Dosimetry
- Contingency plans and corrective actions
- Treatment processes

ISPM 18- Documentation by Facility

Facility Records and Traceability

- Facility and responsible parties
- Commodity
- Target regulated pest(s)
- Packer and grower information
- Lot description and quantity
- Identifying markings
- Absorbed doses (target and measured)
- Date of treatment
- Observed deviations from treatment specification

ISPM 18- Inspection & Certificate

Export inspections ensure the consignment meets the phytosanitary requirements of the importing country

- Documentation verification
- Examination for non-target pests

Phytosanitary certification should include:

- Treated lots
- Date of Treatment
- Target minimum dose
- Verified Dmin

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 0579-0150 and 0 7 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 0579-0150 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
2/201 NGUYEN GIA THIEU STREET, WARD 6, DISTRICT 3
HO CHI MINH CITY, Ho Chi Minh (mncplty) 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 (41675 + 41676)
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 39839 CX (41677 + 41678)
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 (mncplty), 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

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PPQ FORM 203
(JUL 2007)

ISPM 18- Inspection & Certificate

NPPOs should clearly identify the contingency actions to be taken if live pests are found during import inspections:

Target pests- no action unless the required response was not achieved

Non-target regulated pests- no action if the treatment is believed to have been effective

Non-target regulated pests- action if there is insufficient data on efficacy or the treatment is not known to be effective;

Non-target, non-regulated pests- no action

ISPM 18- Additional Items

- Annex 1: Specific Approved Treatments
- Annex 2: Checklist for Facility Approval
- Appendix 1: Estimated Minimum Absorbed Doses for Certain Responses for Selected Pest Groups
- Appendix 2: Research Protocol

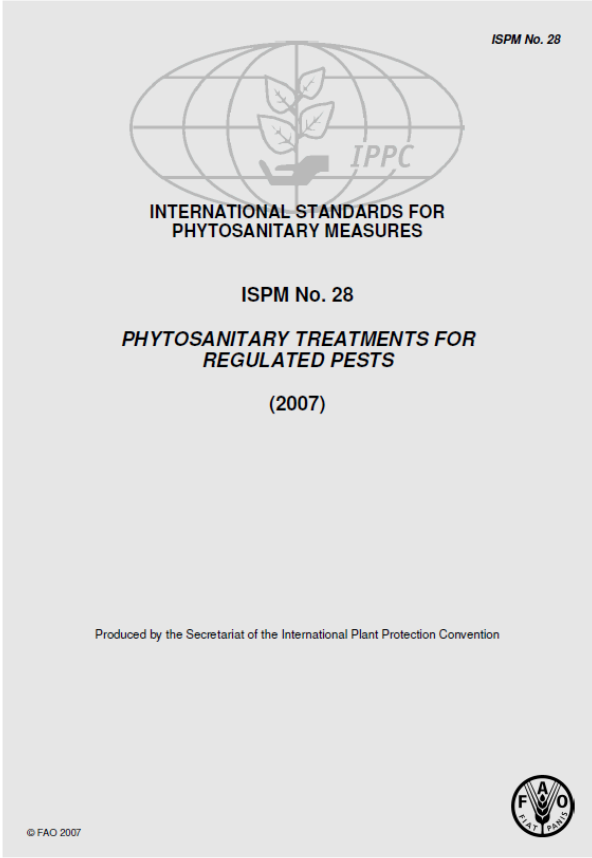
ISPM 28

IPPC recognizes certain treatments as international standards to achieve harmonization, enhance recognition of treatment efficacy, and facilitate trade

NPPO or RPPO can submit data for the evaluation of treatments to the IPPC Secretariat

ISPM 28

The requirements for submitting treatment research data are described in ISPM 28: Phytosanitary Treatments for Regulated Pests



ISPM 28

Submissions are reviewed by the Technical Panel on Phytosanitary Treatments which makes recommendations to the CPM

The CPM either adopts or rejects the treatment as an international standard

If the standard is adopted, it is added as an annex to ISPM 28

ISPM 28

NPPOs are not obliged to used treatments that are adopted as international standards (even for the same pest and regulated article)

Treatments are adopted only for the commodities, target pest(s), and conditions under which they were tested, unless there is sufficient data for extrapolation

ISPM 28- Required Information

Summary Information

- Treatment name
- NPPO/RPPO contact information
- Treatment description – commodity, target pest(s), parameters
- Reason for submission
- Credentials of those conducting research

ISPM 28- Required Information

Efficacy Data

- Source of data
- Lifecycle/stage of target pest(s)
- Statistical level of confidence
- Methods used
- Dose/efficacy curves (if applicable)
- Additional information to support extrapolation (if applicable)

ISPM 28- Required Information

Pest Information

- Species, strain, biotype, etc. (if applicable)
- Conditions under which pests are cultured/reared
- Weight
- Stage of development
- Health
- Method of infestation/infection
- Most resistant life stage

ISPM 28- Required Information

Commodity Information

- Type of regulated article
- Intended use
- Size/shape/weight
- Stage of maturity (if applicable)
- Storage conditions after harvest/quality (if applicable)

ISPM 28- Required Information

Experimental Parameters

- Facilities used
- Equipment used
- Calibration of equipment and accuracy of measurements
- Experimental design
- Level of confidence
- Conditions
- Critical parameters
- How effectiveness was measured
- Dosimetry (if irradiation)

ISPM 28- Feasibility and Applicability

Ease of use

- Risk to operators
- Technical complexity
- Training/expertise required
- Equipment/facilities required
- Cost of treatment facility
- Commercial relevance
- Phytotoxicity data
- Effects on humans, non-target organisms, and environment
- Resistance management
- Have other NPPOs approved the treatment
- Stand alone treatment or part of a systems approach
- Versatility of treatment

Questions?