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BPI QUARANTINE ADMINISTRATIVE ORDER

No. 02
Series of 2008

SUBJECT: RULES AND REGULATIONS FOR THE IMPORTATION, EXPORTATION AND DOMESTIC MOVEMENT OF IRRADIATED PLANTS AND PLANT PRODUCTS AND THE USE OF IRRADIATION AS PHYTOSANITARY TREATMENT

WHEREAS, the Philippines is a member of the International Plant Protection Convention (IPPC), an international treaty securing action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control.

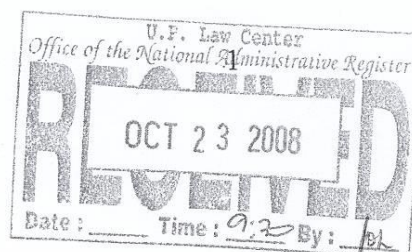
WHEREAS, contracting parties of the IPPC adopts International Standards for Phytosanitary Measures (ISPMs) which are standards, guidelines and recommendations recognized as the basis for phytosanitary measures by World Trade Organization (WTO) members under the Agreement on the Application of Sanitary and Phytosanitary (SPS Agreement).

WHEREAS, in 2003 the Interim Commission on Phytosanitary Measures (ICPM) of the IPPC approved ISPM No. 18, providing technical guidance on the specific procedures for the application of ionizing radiation as a phytosanitary treatment for regulated pests or articles.

WHEREAS, the Bureau of Plant Industry (BPI), being the National Plant Protection Organization (NPPO), is responsible for the phytosanitary aspects of evaluation, adoption and use of irradiation as a phytosanitary measure, and to the extent necessary, should cooperate with other national or international regulatory agencies such as the Philippine Nuclear Research Institute (PNRI) which has the mandate to regulate irradiation facilities using radioactive sources such as cobalt-60 and cesium-137 and the Bureau of Health Devices and Technology (BHDT) which has the mandate to regulate irradiation facilities using radiation emitted by electronic and electrical devices such as electron beam and X-ray.

WHEREAS, irradiation is increasingly accepted internationally as a quarantine treatment, providing effective means of disinfesting/disinfecting plants and plant products for quarantine purposes.

NOW, THEREFORE, pursuant to the provisions of Section 17 of the Presidential Decree No. 1433, the Director of Bureau of Plant Industry hereby issue this Order governing the importation, exportation and domestic movement of irradiated plants and plant products and the use of irradiation as phytosanitary treatment.



GENERAL PROVISIONS

Section 1

Definition of Terms and Abbreviations

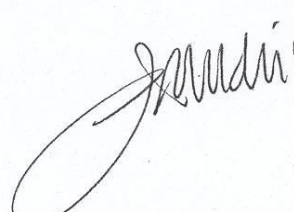
The following terms when used in this Administrative Order shall mean as follows:

Absorbed dose	Quantity of radiation energy absorbed per unit of mass of a specified target. The SI unit is gray (Gy)
Commodity	A type of plant, plant product, or other article being moved for trade or other purpose
Consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate
Domestic movement	Movement of commodity from one locality to another within the country
Dose mapping	Measurement of the absorbed dose distribution within a process load through the use of dosimeters placed at specific locations within the process load
Dosimeter	A device that, when irradiated exhibits a quantifiable change in some property of the device which can be related to the absorbed dose in a given material using appropriate analytical instrumentation and techniques
Dosimetry	A system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use
Efficacy	A defined, measurable and reproducible effect by a prescribed treatment
Exportation	The act of transporting commodities from a local port to a foreign port
Gray (Gy)	Unit of absorbed dose where 1 gray (Gy) is equivalent to the absorption of 1 joule per kilogram
Kilogray (kGy)	Unit of absorbed dose which is equivalent to 1,000 gray (Gy)
Importation	The act of bringing into the country foreign commodities for planting, consumption, manufacturing, domestication or for any other purpose
Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulation

Ionizing radiation	Charged particles and electromagnetic waves that as a result of physical interaction create ions by either primary or secondary processes
Irradiation	Treatment with any type of ionizing radiation
Lot	A number of units of a single commodity, identifiable by its homogeneity of composition, origin, etc., forming part of a consignment
Minimum absorbed dose	The localized minimum absorbed dose (D_{min}) within the process load
Non-Target Quarantine Pest	A pest of quarantine importance that is not known to be neutralized by the irradiation
Pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products
Phytosanitary certification	Use of phytosanitary procedures leading to the issuance of a Phytosanitary Certificate
Plant products	Unmanufactured material of plant origin (including grain) and those manufactured products that, by their nature or that of their processing, may create a risk for the introduction and spread of pests
Plants	Living plants and parts thereof, including seeds and germplasm
Target Quarantine Pest	A pest of quarantine significance that will be neutralized by the approved dose
Treatment	Official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization

Abbreviations:

BPI	Bureau of Plant Industry
BHDT	Bureau of Health Devices and Technology
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
NPPO	National Plant Protection Organization
PNRI	Philippine Nuclear Research Institute
PQS	Plant Quarantine Service



**Section 2
Coverage**

This Order covers the (a) importation, exportation and domestic movement of irradiated living plants, and parts thereof, plant products or unmanufactured material of plant origin and semi-processed plant products or manufactured products that, by their nature or that of their processing, may create a risk for the introduction and spread of pests, and (b) the use of irradiation as a phytosanitary treatment.

IMPLEMENTATION RULE

**Section 3
Irradiation Facility Approval**

Irradiation facility should be approved by the NPPO in the country where the facility is located prior to applying phytosanitary treatments. It covers both local and foreign facility, both for import, export and local trade.

A. Requirements for Approval

1. Local Facility

a. Documentary requirements

- i. Duly accomplished application form
- ii. Copy of Security and Exchange Commission (SEC) Registration or Department of Trade and Industry (DTI) Business Permit, whichever is applicable
- iii. Copy of Mayor's Permit
- iv. Company / facility profile
- v. Tax Identification Number (TIN) and latest Income Tax Return (ITR) where applicable
- vi. Location map of the treatment facility
- vii. License from PNRI (if using radioactive source such as cobalt-60 and cesium-137) or BHDT (if using electrically generated radiation such as electron beam or X-ray)
- viii. Documented Standard Operating Procedures describing in detail the treatment facility system and procedures including all processes from handling, treatment, and post treatment safeguarding of commodity
- ix. List of probable commodities to be treated at the facility

- b. Passed the facility inspection conducted by a BPI authorized officer
- c. Passed the actual facility testing to be supervised by a BPI authorized officer
- d. Facility compliance agreement completed and signed by all appropriate officials
- e. Other requirements that maybe deemed necessary

2. Foreign Facility

- a. Letter of intent for facility approval from the NPPO where the facility is located
- b. Certificate of approval by the NPPO of the country where the facility is located
- c. Philippine verification of the facility and final approval

B. Procedure for Facility Approval

1. Local Facility

- a. Interested local facility / company should file an application for facility approval to the BPI
- b. Original and photocopy of the above-mentioned requirements should be presented
- c. Interested local facility /company should request for facility inspection and testing at the BPI-PQS
- d. A duly authorized Plant Quarantine Officer/Inspector shall inspect and evaluate the treatment facility and shall conduct actual testing
- e. The Plant Quarantine Officer/Inspector shall submit a report of the inspected facility and the result of the actual testing conducted to the Chief of the Plant Quarantine Service
- f. Signing of Facility Compliance Agreement. The agreement shall be concluded between the company/facility and the BPI which shall include the following:
 - BPI's approval of the facility;
 - Monitoring programme administered by BPI;
 - Audit provisions including unannounced visits;
 - Free access to documentation and record of the treatment facility; and
 - Corrective action to be taken in cases of non-compliance.
- g. Recommendation by the PQS Chief prior to the final approval of the BPI Director
- h. Certificate of Approval shall be issued with the assigned code

2. Foreign Facility

For foreign facility, the NPPO of the country where the facility is located shall endorse the application for facility approval to the BPI. The BPI shall review and evaluate the application and if necessary shall conduct an actual visit of the facility for verification and final approval.

C. Treatment

The use of irradiation as a phytosanitary measure shall prevent the introduction or spread of regulated pests. This may be realized by achieving certain responses in the targeted pest(s) such as: mortality, preventing successful development (e.g. non-emergence of adults), inability to reproduce (e.g. sterility), or inactivation.

Ionizing radiation may be provided by radioactive isotopes (gamma rays from cobalt-60 or cesium-137), electrons generated from machine sources (up to 10 MeV) and X-ray machine (up to 5MeV).

Treatment dose for a specific commodity must be determined based on science through bilateral agreement between Philippines and its trading partner. For local trade, the NPPO shall issue and adopt guidelines for specific target pest that may be developed in the future.

The following are the treatment requirements:

- Treated commodities shall be certified and released only after dosimetry measurements confirm that the Dmin was met
- Re-treatment of consignments may be allowed, provided that the maximum absorbed dose is within the limits allowed by the importing country
- Treatment shall be done only by facilities approved by the Bureau of Plant Industry
- Treatment shall be done in the presence of a Plant Quarantine Officer/ Inspector
- Dose rate, treatment time, temperature, humidity, and ventilation should be carefully considered when conducting treatments

D. Dosimetry

1. Calibration

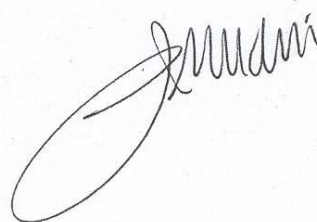
- All components of the dosimetry system shall be in accordance with international dosimetry standards
- BPI shall assess performance of the dosimetry system

2. Dose mapping

- Dose mapping shall be done in accordance with documented standard operating procedures.
- Dose mapping shall be conducted to fully characterize the dose distribution within the irradiation chambers and commodity, and demonstrate that the treatment consistently meets the prescribed requirements under defined and controlled conditions.
- Independent dose mapping shall be done for incomplete as well as first and last process loads (for continuous irradiation) to determine if the absorbed-dose distribution is significantly different from a routine load and to adjust the treatment accordingly.

3. Routine Dosimetry

- As part of the verification process, an accurate measurement of absorbed dose in a consignment should be ensured to determine and monitor treatment efficacy.
- The required number, location and frequency of the measurements should be prescribed based on the specific equipment, processes, commodities, relevant standards and phytosanitary requirements.
- Dosimeters verification shall be carried out to evaluate for stability against the effects of variables such as light, temperature, humidity, storage time, and the type and timing of analyses required.

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E. Packaging and Labeling

1. Packaging

In order to avoid infestation after irradiation, commodities should be packed in materials that provide an effective barrier to re-infestation. Packaging shall conform to the requirements of the NPPO of the importing country. The size and shape of containers are determined, in part, by the operating characteristics of the irradiation facility. These characteristics include the product transport systems and the irradiation source, as they affect the dose distribution within the container.

2. Labeling

Packages/ boxes shall be marked with at least the following identifying features to allow identification of treatment lots and trace-back:

- name of product and quantity
- treatment facility code
- packing facility identification number and location
- treatment facility identification number and location
- grower/production area code
- treatment lot numbers
- prescribed treatment
- date of packing
- treatment date
- radura symbol (optional)

All packages should be labeled "*Treated with Radiation*" or "*Treated by Irradiation*".

F. Verification

Adequacy of treatment facilities and processes shall be verified through monitoring and audit of facility treatment records that include, direct treatment oversight. The level of oversight should be sufficient to detect and correct deficiencies promptly.

G. Documentation by the treatment Facility

BPI shall be responsible for monitoring records and documentation of the treatment facility and ensuring that records are available to concerned parties.

1. Documentation of procedures

Documented procedures help ensure that commodities are consistently treated as required. At a minimum, an agreed written procedure should address the following:

- consignment handling procedure before, during and after treatment;
- orientation and configuration of the commodity during treatment;
- critical process parameters and the means for their monitoring;
- dosimetry;

- contingency plans and corrective actions to be taken in the event of treatment failure or problem with critical treatment processes;
- procedures for handling rejected lots; and
- labeling, recordkeeping, and documentation requirements.

2. Facility records and traceability

Treatment facility operators shall keep records which shall be available to BPI for review when necessary and shall be kept for at least one year. Records that maybe required include:

- minimum and maximum absorbed doses (target and measured);
- name of clients and their details;
- commodity treated;
- purpose of treatment;
- lot size, volume and identification, including number of articles or packages;
- date of treatment; and
- any observed deviation from treatment specification.

SECTION 4

Accreditation of Exporter and Packing Facility

All exporters intending to export irradiated plants and plant products shall apply for accreditation at the nearest Bureau of Plant Industry-Plant Quarantine Service (BPI-PQS) office with the following requirements and procedure:

A. Requirements for Accreditation

1. Documentary Requirements

- i. Duly accomplished application form
 - ii. Copy of Security and Exchange Commission (SEC) Registration or Department of Trade and Industry (DTI) Business Permit, whichever is applicable
 - iii. Copy of Mayor's Permit
 - iv. Company / facility profile
 - v. Tax Identification Number (TIN) and Latest Income Tax Return (ITR) where applicable
 - vi. Location map of the packing facility
2. Standard Operating Procedure of the packing house
 3. Other requirements that maybe deemed necessary

B. Procedure for Accreditation

1. All interested exporters shall file an application for accreditation to the nearest BPI-PQS with the above-mentioned requirements.
2. BPI shall validate the application and whenever necessary, the BPI-PQS shall conduct an interview which shall cover Plant Quarantine Law and Rules and Regulations.

3. Interested exporters should request for packing facility inspection to BPI-PQS.
4. A duly authorized Plant Quarantine Officer/Inspector shall inspect and evaluate the packing house facility.
 - Packing house facility should be in good condition;
 - Packing house should be hygienically maintained and sprayed with insecticides; to include surrounding premises so as to exclude the entry of pests;
 - Packing house must be equipped with net (less than 1.6x1.6mm) for any opening to prevent entry of pests;
 - Packing house must have sufficient water supply for cleaning;
 - Packers should wear hairnets within the packing house; and
 - Packing house should have sufficient lighting.
5. The Plant Quarantine Officer/Inspector shall submit a report of the inspected packing house facility to the Chief of the Plant Quarantine Service.
6. Recommendation by the Chief PQS for final approval of the BPI Director.
7. Upon completion of the abovementioned requirements, BPI-PQS will issue a Certificate of Accreditation with assigned code.
8. Any accredited exporter who violates the Plant Quarantine Law, rules and regulations of this protocol will be delisted as an accredited exporter and its Certificate of Accreditation shall be revoked. Re-accreditation shall only be possible upon compliance of all corrective measures based on thorough plant quarantine investigation.

SECTION 5

Suspension and Reinstatement of Facility

A. Suspension

The following are the grounds for suspension:

1. Exporter / Packing Facility
 - Non compliance with the set standards for a packing house facility
 - Tampering/alterations of the Phytosanitary Certificate
 - Tampering/alterations of labels of the packages or boxes intended for export
 - Problems detected by the Plant Quarantine Officer during audit.
 - Failure to inform the BPI-PQS of the changes made in the packing facility and in the operational procedures that may substantially affect the export
 - Packing of commodity without the presence of the Plant Quarantine Officer
2. Treatment Facility
 - Repeated non-compliance (twice) of treatment facilities with the set standards and regulations shall result to suspension of the facility
 - Problems detected by the Plant Quarantine Officer during audit.
 - Conduct of treatment without the presence of the Plant Quarantine Officer.
 - Failure to inform the BPI-PQS of the changes made in the facility and in the operational procedures that may substantially affect any aspect of the treatment process

B. Re-instatement of Facility

Re-instatement of the packing house and treatment facility shall only be granted when corrective measures have been undertaken.

C. Procedure for re-instatement

1. The packing/treatment facility shall request for re-instatement to the BPI.
2. BPI shall review and evaluate the request.
3. BPI shall visit the facility (packinghouse and/or treatment facility) and conduct inspection.
4. BPI shall conduct actual testing of the treatment facility (calibration, dose mapping and routine dosimetry) for certification.
5. Approval of BPI for re-instatement.

Section 6 Inspection and Phytosanitary Certification

A. Export Inspection

1. Packinghouse Facility
 - a. A BPI Plant Quarantine Officer shall be assigned to inspect the packing process at the packing area.
 - b. BPI Plant Quarantine officer shall verify that all cartons are properly packed, sealed and labeled.
 - c. The BPI Plant Quarantine Officer shall carry out inspection on specified sample size based on protocol agreed with a trading partner.
2. Irradiation Facility
 - a. Treated commodities shall be separated from non-treated commodities.
 - b. Treated commodities shall be safeguarded in holding rooms to prevent unauthorized entry and re-infestation.
 - c. Documentation verification shall be done by the BPI to check for completeness and accuracy as the basis for certifying the treatment.
 - d. Treated commodities shall be properly labeled and must bear the appropriate markings prior to release.

B. Phytosanitary Certification

BPI shall issue Phytosanitary Certificate signed by a deputized Plant Quarantine Officer upon compliance with the requirements.



C. Import Inspection

Import inspection shall be carried out in accordance with bilateral agreement between Philippines and the exporting country taking in consideration the following:

- target pest/s
 - non-target pest
 - verification of efficacy of the treatment
1. All importers should apply for inspection/clearance at least 24 hours prior to arrival of the consignment for all commodities treated with irradiation.
 2. Upon arrival, commodities shall be subjected to inspection and clearance by the Plant Quarantine Officer / Inspector.
 3. All shipment should have the proper label/markings.
 4. The following measures shall be followed in the event of the following situations:

Detection of target pest(s) when mortality is not the required response

- Detection of live stages of target pests should not be considered treatment failure resulting in non-compliance, unless the integrity of the treatment system is inadequate
- Laboratory or other analyses may be performed on surviving target pest(s) to verify treatment efficacy

Detection of target pest(s) when mortality is the required response

- Live target pests maybe found when transport times are short, but should not normally result in consignment refusal, unless the established mortality time has been exceeded

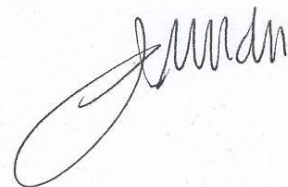
Detection of pests other than target pest(s)

- Should be assessed for risk posed and appropriate measures done, taking into consideration the effect of treatment on the non-target pest(s)
- Consignment maybe detained and any appropriate action may be taken by the BPI

D. Notification of Non-Compliance and Emergency Actions

The BPI should immediately notify the NPPO of the exporting country if they have identified non-compliance with specified phytosanitary requirements. This is to give the exporting country an opportunity to investigate instances of apparent non-compliance, and correct as necessary. The following maybe considered as significant failures:

- Failure to comply with documentary requirements, including:
 - a. Absence of phytosanitary certificates
 - b. Uncertified alterations or erasures to phytosanitary certificates
 - c. Serious deficiencies in information on phytosanitary certificates
 - d. Fraudulent phytosanitary certificates



- Prohibited consignments
- Evidence of failure of specified treatments
- And other significant failures

Notification should include information as stipulated in ISPM No. 13 "*Guidelines for the Notification of Non-compliance and Emergency Action*".

For non-compliance, the exporting country should investigate significant instances of non-compliance to determine the possible cause with a view to avoid recurrence. Upon request, the result of the investigation should be provided to the BPI.

Emergency actions maybe undertaken by the Philippines based on the current phytosanitary situation of the consignment.

APPENDICES

Bilateral agreements and detailed procedures (eg. Operational Work Plan and official forms) shall form part of this Order.

LEGAL SANCTIONS

Any deficiencies in complying with the rules and regulations for the movement of irradiated plants and plant products and the use of irradiation as phytosanitary treatment or any violations of any provisions of this Administrative Order shall be ground for the imposition of fines, suspension or revocation of the accreditation after due notice.

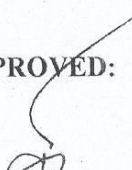
REPEALING CLAUSE

All existing rules and regulations inconsistent with this Order are hereby modified, revoked or repealed accordingly.

EFFECTIVITY


This Order shall take effect fifteen (15) days after its publication in a national newspaper of general circulation.

APPROVED:


ARTHUR C. YAP
Secretary

08 August 2008


JOEL S. RUDINAS, CESO IV
BPI DIRECTOR

DEPARTMENT OF AGRICULTURE

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Received : 08/15/2008 10:33 AM