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ORGANIZACION NORTEAMERICANA DE PROTECCION A LAS PLANTAS
CANADA UNITED STATES MEXICO

NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM # 4
Guidelines for the Use of Irradiation as a Phytosanitary Treatment

The Secretariat of the North American Plant Protection Organization
Nepean, Ontario, Canada
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CONTENTS

REVIEW

NAPPO Standards for Phytosanitary Measures are subject to periodic review and to amendment. The next review for this Standard is October 2001. A review of any NAPPO Standard may be initiated at any time upon the request of a NAPPO member country.

ENDORSEMENT

This Standard was approved by the North American Plant Protection Organization (NAPPO) Executive Committee on April 18, 1997.

APPROVED BY:

Jean Hollebone
CANADA

Alfred S. Elder
UNITED STATES

Javier Trujillo Arriaga
MEXICO

AMENDMENT RECORD

Amendments to this Standard will be given a consecutive number, dated and filed with the NAPPO Secretariat.

DISTRIBUTION

This Standard is distributed by the Secretariat of the North American Plant Protection Organization to all NAPPO members, to the FAO IPPC Secretariat, to IICA, and to the Administrative Heads of the Regional Plant Protection Organization (RPPOs). Copies are available to government and non-government organizations within and outside of NAPPO upon request to the NAPPO Secretariat.

NAPPO GUIDELINES FOR THE USE OF IRRADIATION AS A PHYTOSANITARY TREATMENT

INTRODUCTION

SCOPE

This standard offers guidance for the evaluation, adoption, and use of irradiation as a phytosanitary treatment. It is designed to encourage consistency by providing essential information concerning the technical and operational aspects of employing irradiation as a

treatment for plant pests.

The use of irradiation to produce sterile organisms for release in pest control programs is a unique phytosanitary application that is not directly addressed in this standard, but may be developed as an adjunct standard at a later date. The use of irradiation to preserve commodities or enhance quality, or for any purpose other than a quarantine treatment, is outside the scope of this standard.

Whether irradiation is considered or used in any given circumstances may be dependent on variables beyond the control and authority of the National Plant Protection Organization (NPPO) of the country in question. Therefore, it is also beyond the purview of this document to represent authority for the acceptance and use of irradiation.

REFERENCES

American Society for Testing and Materials, 1995. *ASTM Dosimetry Standards for Radiation Processing (from the Annual Book of ASTM Standards).* ASTM Subcommittee E10.01, 173 pp.

International Consultative Group on Food Irradiation (ICGFI), 1991. Doc. No. 7: *Code of Good Irradiation Practice for Insect Disinfestation of Fresh Fruits.* ICGFI, 13 pp.

USDA, 1995. The Application of Irradiation to Phytosanitary Problems: Position Discussion Document IV. APHIS, PPQ, 23 pp.

USDA, 1996. Notice of Policy: The Application of Irradiation to Phytosanitary Problems. Docket No. 95-088-1, *Federal Register*, Rules and Regulations, May 15, 1996, pp. 24433-24439.

DEFINITIONS, ABBREVIATIONS AND ACRONYMS

Absorbed dose (= dose)	Quantity of radiation energy absorbed per unit of mass of a specified material. The unit of absorbed dose is the gray (Gy) where 1 gray is equivalent to the absorption of 1 joule per kilogram (= 100 rad).
Absorbed-dose mapping	Measurement of the absorbed-dose distribution within a process load through the use of dosimeters placed at specified locations within the process load.
Absorbed-dose rate	The absorbed dose in a material per unit time interval, i.e., the quotient of dD by dt (D = dD/dt). The unit for absorbed-dose rate is gray per second ($Gy.s^{-1}$)
Dmax	The localized maximum absorbed dose within the process load.
Dmin	The localized minimum absorbed dose within the process load.

Dose uniformity ratio	Ratio of the maximum to the minimum absorbed dose within the process load. The concept is also referred to as the max/min dose ratio. U = Dmax/Dmin
Dosimeter	A device that, when irradiated, exhibits a quantifiable change in some property of the device which 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.
Efficacy (treatment)	Capability of a treatment to produce a defined, measurable, and reproducible desired effect on pests.
Gray (Gy)	Unit of absorbed dose where 1 Gy is equivalent to the absorption of 1 joule per kilogram. 1 Gy = 1 $J.kg^{-1}$ Formerly, the special unit for absorbed dose was the rad. 1 rad = 10^{-2} $J.kg^{-1}$ = 10^{-2} Gy
Ionizing radiation	Any type of radiation consisting of charged particles, uncharged particles, or photons, that as a result of physical interaction, creates ions by either primary or secondary processes. Charged particles could be positive or negative electrons, protons, or other heavy ions, and uncharged particles could be X-rays, gamma rays, or neutrons. (Note: positive electrons, protons, heavy ions, or neutrons are not approved for food irradiation).
Irradiation	The purposeful application of ionizing radiation (gamma rays, x-rays, or electrons) to a product (device or material) to achieve a desired benefit. Gamma rays come from radioactive cobalt-60 (^{60}Co) or cesium-137 (^{137}Cs). X-rays (technically referred to as bremsstrahlung) are obtained by using high energy electrons from an electron accelerator to strike a target. Electrons from an accelerator can also be used to penetrate the product directly.
Kilogray (kGy)	Measure of absorbed dose. 1kGy = 1,000 Gy.
Label dosimeter	A device that can be affixed to an article to be irradiated, and which exhibits a quantifiable change in property which can be related to absorbed dose. This change in property can be measured in situ. Note: no such devices that have the properties of a dosimeter are commercially available for the dose levels appropriate to quarantine treatments.
Measurement traceability	The ability to demonstrate and document on a continuing basis that the measurement results from a particular measurement system are in agreement with comparable measurement results obtained with a national, international, or other identifiable and accepted standard and to a specified uncertainty.

Pest (plant)	Any biotic agent capable of causing injury or damage to plants or plant products.
Phytosanitary treatment (treatment)	Officially authorized procedure for killing, removal, or rendering infertile of plant pests.
Process load	A volume of material with a specified loading configuration irradiated as a single entity.
Quarantine security (negligible pest risk)	Inspection, treatment, and safeguard procedures which are carried out at a level where artificial introduction of plant pests is not likely to occur.
Rad (rad or radiation absorbed dose)	Special unit for absorbed dose, that is being superseded by the gray (Gy) 1 Gy = 100 rads 1 kilogray = 100,000 rads
Systems approach	A defined set of phytosanitary procedures, at least two of which have an independent effect in providing for the pest-free movement of commodities.
System Integrity	Verifiable assurance that a defined set of phytosanitary procedures are efficacious and properly conducted.
Target minimum dose	The minimum dose required for efficacy and accounting for uncertainty in dosimetry.
Validation	Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product (quarantine security) meeting predetermined specifications and quality characteristics.

OUTLINE OF REQUIREMENTS

NAPPO countries are dedicated to using the most up-to-date, appropriate, and least intrusive technology to achieve quarantine security and facilitate safe trade. Research and experience have demonstrated that irradiation is a technology that can be effectively and practically employed as a phytosanitary treatment in an increasing number of situations. It is recognized that the addition of irradiation to the array of pest risk management tools available to the NAPPO countries is important for providing alternatives to traditional treatments such as fumigation. Employed as a single treatment or as a component of a pest mitigation system, irradiation offers numerous opportunities for developing new treatments and augmenting existing pest risk management programs.

GENERAL REQUIREMENTS

1. Administration

1.1 National Plant Protection Organizations (NPPOs) should have the ability to evaluate, adopt, and authorize irradiation treatments done for quarantine pests.

1.1.1 NPPOs should ensure that suitable expertise is available and used for the evaluation of technical and operational aspects of the technology and its application for phytosanitary treatments.

1.1.2 NPPOs should ensure that suitable expertise is available and used for designing research and evaluating the results of research done or offered to support the adoption of irradiation treatments.

1.2 Policies, procedures, and requirements developed for irradiation treatments should be consistent with those associated with other phytosanitary treatments, except where the use of irradiation requires a different approach or presents unique circumstances.

1.3 The intended end use of the product to be treated should not be jeopardized by the irradiation treatment.

1.4 Requirements designed for imports should be consistent with those designed for exports.

1.5 To the extent possible, NPPOs should harmonize with other national and international regulatory agencies to avoid overlapping and conflicting requirements, inconsistent or unfair requirements and duplication of authority. This includes phytosanitary authorities as well as regulatory bodies concerned with the development, approval, safety, and application of irradiation or the distribution, use, or consumption of irradiated products.

1.6 The NPPO should focus resources on those treatments deemed to have the greatest potential need, use, and benefit. The availability of practical alternatives, the environmental impact of options, the feasibility of general use, and the importance of the commodity to trade should be considered.

1.7 Program protocols or equivalent documentation describing the details of a program surrounding irradiation authorizations for facilities/commodities will be maintained and made publicly available by the NPPO establishing the requirements and the NPPO implementing the program (certifying treatments). Regulations, manuals, work plans, or combinations of these and similar information may be used.

2. Quarantine Security

2.1 Measures aimed at reducing pest presence prior to treatment are encouraged but should not be required for single treatments attaining quarantine security. However, a very low infestation rate is important for alleviating regulatory concerns arising from the detection of living pests in the irradiated product, particularly if the pests are capable of moving from the treated product.

2.2 The endpoint for quarantine security in irradiation treatments may be defined in terms of mortality, sterility, or other criteria such as the inability of mature life stages (e.g. adult insects) to fly or spread. The minimum requirement is that survivors are not able to reproduce and are not confused with untreated pests encountered inside and outside the commodity.

2.2.1 Mortality may be defined by different statistical methods with different

time limitations (e.g. 20 survivors upon completion of a treatment, no survivors within 6 days after completion of the treatment, etc.).

2.2.2 Sterility (the inability to reproduce) should be considered an appropriate endpoint for organisms that remain in or on the host. These organisms pose no concern for regulatory actions provided it can be verified that the host has been properly treated.

2.3 Live stages of pests found in a commodity following an approved irradiation treatment will be presumed to have been effectively treated unless evidence exists to indicate that treatment system integrity was inadequate. Laboratory or other analyses may be performed on surviving pest organisms to verify efficacy. Such analyses should only be required infrequently as part of monitoring unless there is evidence to indicate problems in the treatment process.

2.4 It is essential for quarantine purposes that surviving pests are rendered unable to reproduce and it is desirable for pests to be unable to emerge from the commodity unless they can be practically distinguished from a non-irradiated pest.

3. Treatment

3.1 Ionizing energy (radiation) may be provided by isotopes (gamma rays from cobalt-60 or cesium-137), electrons generated from machine sources, or by x-rays. The source and equipment used for phytosanitary treatments must be capable of safely and effectively irradiating commodities to the required specifications.

3.2 Irradiation treatment must be carried out to ensure that the minimum absorbed dose (Dmin) was fully attained throughout the commodity to provide the prescribed level of quarantine security.

3.2.1 Treatments must be proven with adequate dosimetry in accordance with relevant internationally accepted standards.

3.2.2 A target minimum absorbed dose must be achieved that accounts for the uncertainty associated with the dosimetry system.

3.3 Irradiation treatment can be applied as an integral part of packing operations or it may be done afterward at a central location such as the port of embarkation. Treatment may also be performed at the port of arrival or a designated location in a third country or the country of final destination when safeguards are deemed to be adequate and transit movement of the untreated commodity is operationally feasible.

3.4 The irradiation treatment may be applied to bulk or continuous unpackaged commodities (such as grain), or the commodities may be packaged at the time of treatment.

3.5 Treated commodities will only be certified and released after dosimetry

measurements have been evaluated and recorded.

4. Dose and Dosimetry

The purpose of dosimetry in irradiation treatment is to ensure that the required absorbed dose for a particular commodity has been delivered. This is accomplished by dose mapping with specific commodities and process load configurations to determine the minimum absorbed doses, their locations in the process load, and the appropriate treatment time needed to satisfy established requirements.

4.1 Generic doses may be developed and approved for a pest or pest group (irrespective of the commodity), or a commodity or commodity group (irrespective of the pest).

4.2 Designation of the lower dose limit is essential to the approval of irradiation treatments for phytosanitary purposes. Definition of the upper dose limit is not critical to determining quarantine security but may be important from a quality standpoint and can be a regulatory concern under other authorities. NPPOs will not be concerned with defining the upper dose limit for quarantine treatment purposes except to the extent that it may be necessary to determine the feasibility of a particular treatment.

4.3 Treatments with doses higher than what is indicated as effective by available data may be adopted to expedite the availability of new treatments while providing a measure of safety. This will only be done when the data are judged to be inconclusive to the extent necessary for approving a lower absorbed dose. All approved doses will be subject to adjustment, and treatment requirements amended when new information indicates that such changes are technically justified.

4.4 An accurate measure of absorbed dose is critical to determining and monitoring efficacy. The required number and frequency of these measurements must be prescribed based on the specific equipment, processes, commodities, and relevant standards.

4.5 Dosimeters must be appropriate for the treatment conditions. Dosimeters should be evaluated for stability against the effects of variables such as light, temperature, humidity, storage time, and the type and timing of analyses required.

4.6 Absorbed dose must be measured using dosimeters calibrated to a recognized national or international standard and recalibrated at appropriate intervals.

4.7 Analytical equipment, personnel, and processes used in the analysis of dosimeters are critical for accurate dosimetry. The performance and quality of these factors should be checked at routine intervals as determined by the dosimetry system and relevant standards.

4.8 The dose distribution within the commodity must be determined by dose mapping, demonstrating that the treatment consistently meets prescribed

requirements under defined and controlled conditions.

4.8.1 Dose mapping must be performed in accordance with bilaterally agreed upon processes or recognized internationally accepted standards.

4.8.2 Dosimetry must consider variations due to density and composition of the material treated, variations in shape and size, variations in orientation of the product, stacking, volume, and packaging. Dose mapping of the product in every geometric packing configuration, arrangement, and product density that will be used during routine treatments will be required prior to the approval of a facility.

4.8.3 The number of dosimeters used for routine treatment shall be in accordance with relevant internationally accepted standards.

4.8.4 The number of dosimeters used for research will be determined by the type of data to be collected, but should be at least equivalent in intensity and precision to the dosimetry that would be used for routine commercial applications.

4.8.5 Independent dose mapping for incomplete (partially-filled) as well as first and last process loads is required to determine if the absorbed-dose distribution is significantly different from a routine load and to adjust the treatment accordingly.

4.9 Reference dose positions within the process load may be used when the actual positions for measuring Dmin are not readily accessible during routine treatments. The differences between reference dose positions and the Dmin positions must be consistent and documented.

5. Facilities

The qualification (approval, certification, or accreditation) of facilities and treatment applicators is essential for evaluating the ability of a facility to accurately and consistently deliver doses over the range of conditions and commodities associated with the authorizations in question. Qualification is also important for understanding the unique characteristics of a particular facility in order to assess the degree to which physical and process designs affect safeguarding.

5.1 Treatment facilities must be licensed by relevant national authorities. When not conflicting with national authority, compliance with the criteria of the International Inventory of Authorized Food Irradiation Facilities, established by the International Consultative Group on Food Irradiation (ICGFI) is also recommended for facilities treating food items.

5.2 Treatment facilities should be subject to prior approval (qualification, certification, or accreditation by NPPOs) and to periodic unannounced monitoring.

5.2.1 Recertification should be done on an annual basis or following repairs, modifications, or adjustments in equipment or processes that affect the

delivered dose.

5.2.2 Approval should be based on a common set of criteria plus those specific to the site and commodity programs.

5.2.3 A significant increase or decrease in radioisotope or major modification to equipment which impacts the delivered dose must be reviewed by the NPPO and may require additional dose mapping.

5.2.4 Significant variance in dose delivery (based on monitoring of dosimetry records) may provide the basis for requiring recertification.

5.2.5 The NPPO in the importing country or the exporting country may, by cooperative agreement, defer to the other NPPO or other agreed upon authorities for the monitoring, certification, and approval of facilities for phytosanitary treatments.

5.3 The adequacy of treatment facilities and processes should be routinely verified through direct treatment oversight and monitoring (audit) inspections of facility treatment records. Direct, continuous supervision of treatments should not be necessary provided treatment programs are properly designed to provide a high degree of system integrity for the facility, process, and commodity in question. This level of oversight should be sufficient to detect and correct deficiencies in a timely fashion.

5.3.1 The degree of treatment oversight required for a facility is reduced by:

- Periodic bilateral approval of the treatment facility by NPPOs of both the importing and exporting countries.
- An effective monitoring and certification program administered by the NPPO of the country where treatments are conducted.
- Bilateral approval of a program protocol including provisions for unannounced monitoring and free access to treatment records.
- Demonstrated compliance with national and international regulations and standards for irradiation processing.
- Well-maintained facilities and a history of trouble-free treatments.

5.4 Memorandums of Understanding (MOUs), compliance agreements, or similar documented agreements between NPPOs and the treatment applicator/facility should be used to outline process requirements and assure that responsibilities, liabilities, and the consequences of non-compliance are clearly understood. Such documents may also serve to strengthen the enforcement capability of the NPPO should corrective action be necessary.

6. System Integrity

Confidence in the adequacy of irradiation treatment rests with the assurance that the treatment is efficacious against the pest under specific conditions and the treatment has been properly conducted and the commodity adequately safeguarded.

Credible efficacy research and appropriate dosimetry provide assurance that only efficacious treatments are approved. Well-designed and closely monitored systems for treatment delivery and safeguarding assure that treatments are properly conducted.

6.1 Program protocols ensure that commodities are consistently treated as required. A program protocol describing process controls and operational parameters is usually developed to provide the operational details necessary for a specific authorization and/or facility. The program protocol may be included in the regulations, a work plan, or similar document. At a minimum, program protocols should address the following:

- Commodity handling procedures 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 problems with critical treatment processes.
- Procedures for handling rejected lots.
- Labeling, record keeping and documentation requirements.

6.2 Product quality is not a phytosanitary concern, but systems designed to assure quality may have a significant effect in reducing pest risk. Whenever possible, phytosanitary programs should be integrated with quality control systems associated with irradiation treatment.

6.3 Treated and untreated commodities must be adequately segregated, clearly identified, and handled under conditions that will safeguard against cross-contamination or mistaken identity.

6.3.1 A fail-safe means of moving the commodity from receiving areas to treatment areas without mistaken identity or risk of cross-contamination is essential. Appropriate procedures specific to each facility and commodity treatment program should be agreed upon in advance.

6.3.2 Commodities that are unpackaged or exposed in packaging require safeguarding immediately following treatment to ensure that they are not

subject to reinfestation, reinfection, or contamination afterward.

6.4 Packaging prior to irradiation may be desirable to prevent re-infestation if irradiation is done at the export source, or to prevent the accidental escape of target pests if treatment is done at the destination.

6.4.1 Packaging materials and processes may be subject to regulations and requirements under other authorities.

6.5 Products not treated according to required schedules must be removed and discarded or otherwise eliminated from shipments for export. Re-treatment is not generally allowed unless there is a high degree of confidence that re-treatment will not result in misidentification or cross-contamination, or conflict with the requirements of other authorities.

6.6 Packages must be marked and labeled with treatment lot numbers and other identifying features allowing the identification of treatment lots and trace-back (packing and treatment facility identification and locations, dates of packing and treatment).

7. Documentation and Monitoring

7.1 Packers and treatment facility operators should be required to keep complete records concerning sources (growers) supplying commodities for treatment. These records should be available to the NPPO for review in the event a trace-back is necessary. Trace-back capability is especially important when pests other than the target pests have been detected.

7.2 The treatment operator must have reliable and probative evidence of correct treatment for each lot certified. Complete dosimetry records must be kept by the treatment facility for at least 1 full year after treatment. In most cases, these records are required under other authorities, but these records must also be available to the NPPO for review at any time. Other information that should be recorded includes:

- Identification of facility and responsible parties.
- Identity of commodities treated
- Purpose for treatment
- Target quarantine pest(s)
- Packer, grower, source identification
- Lot size, volume, and identification, including number of articles or packages
- Identifying markings or characteristics
- Quantity in lot
- Absorbed dose -target and measured
- Date of treatment

7.3 Calibration and quality programs should be documented by the facility operator.

7.4 Phytosanitary certification in accordance with the International Plant Protection Convention (IPPC) should be used and recognized as verifying the successful

completion of an irradiation treatment. Certification must specifically identify the treated lot and record the target minimum dose and the verified minimum dose. The maximum dose and other relevant information may also be provided so long as this information is limited to what is necessary and technically justified for phytosanitary purposes.

7.5 Verification of treatment by an authority other than the NPPO, by the treatment applicator, or by a commercial entity may be acceptable for certification purposes. Verification authorities should be able to demonstrate a high level of competency and integrity, and must be bilaterally approved.

8. Research

Irradiation as a single treatment, part of a multiple treatment, or combined with other pest mitigation measures as a component of a systems approach, must have a scientifically demonstrated level of efficacy just as other treatments. However, because irradiation treatments are based on absorbed dose, confirmatory testing to demonstrate efficacy under commercial conditions may not be required.

8.1 It is the responsibility of the NPPO to ensure that prescribed treatments are efficacious against quarantine pests. The research and commercial sector share the responsibility for ensuring that treatments are also practical for commercial use. However, data addressing the commercial feasibility of treatments, including phytotoxicity and issues of quality can be useful to the NPPO in prioritizing the resources devoted to treatment approval.

8.2 Treatment data must demonstrate efficacy for a defined level of quarantine security against the most tolerant life-stage of the pest(s) of concern.

8.3 The efficacy of the treatment as demonstrated against pests in vitro is the primary criterion for approval in most cases. Efficacy should first be demonstrated with laboratory scale tests designed to provide results that can be analyzed statistically to hypothesize the parameters necessary to attain a defined level of quarantine security.

8.4 Experiments should be designed so that statistically meaningful data can be generated. Whenever possible, the design of the studies should be approved by the NPPO prior to doing the research.

8.4.1 Data for different or closely related organisms or species should be considered and may provide the basis for reducing testing intensity. Such data may also serve as surrogate data for decision making when appropriate tests cannot be designed for the pest(s) of concern.

8.4.2 Substitute organisms may be used when appropriate tests cannot be designed for the pests of concern.

8.5 The equipment, processes, and dosimetry for treatment research should be well

documented and standardized whenever possible.

8.6 Details concerning the condition of commodities both before and after treatments, as well as the condition and viability of the pests and survivors, should be reported.

TECHNICAL REQUIREMENTS

The primary technical inputs needed for the evaluation, approval, and use of irradiation as a phytosanitary treatment are: (1) sufficient research data and technical expertise and facilities to be able to propose, evaluate, approve, and administer treatments; and (2) operational work plans describing specific pests, commodities, facilities and processes in the context of the relevant authorities and programs. The requirements for particular irradiation treatment programs need to be developed on a case-by-case basis after consideration of the pests, commodities, facilities, and processes involved.

Irradiation treatments done for phytosanitary purposes will fall into one of several categories. Technical requirements or specific supplementary standards may be developed for each of the following:

- The disinfestation of fruits and vegetables for arthropods, including fruit flies.
- Treatments for diseases and nematodes.
- Devitalization treatments for propagative/propagatable material.
- Growth inhibition treatments.
- Treatments for non-food articles (wood products, cut flowers, etc.).
- Pest sterilization for control activities.

APPENDIX

(No appendices currently attached)