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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 95–088–1]

The Application of Irradiation to Phytosanitary Problems

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of policy.

SUMMARY: This document sets forth a policy statement that shares positions and policies of the Animal and Plant Health Inspection Service (APHIS) concerning the use of irradiation as a treatment for plant pests of quarantine significance.

In preparing this document, we have reviewed and evaluated pertinent and contemporary information concerning irradiation as a phytosanitary treatment or potential treatment. We have examined this information against the background of regulatory and operational parameters associated with APHIS, Plant Protection and Quarantine's (PPQ's) mission and authority. The objective of this effort has been to generate a reference document that describes policies, procedures, and regulations specifically related to irradiation as a phytosanitary treatment. This document is designed for review and comment.

ADDRESSES: There are several ways to comment on this document. Because we hope to develop a dialogue among persons interested in contributing to the improvement of these policies, the preferred method of commenting is to subscribe to an e-mail mailing list we are establishing for the discussion of the policy issues. After you subscribe, on an ongoing basis you will receive e-mail copies of all comments submitted to the mailing list. Those wishing to subscribe to this service should send an e-mail message to ''majordomo@info.aphis.usda.gov''—without the quotation marks—and leave the subject area empty. In the body of the message, type ''subscribe irrad''—again without the quotes—and then send the message.

You can also subscribe to this mailing list or file individual e-mail comments using a form contained in a World Wide Web site devoted to this document. The site also contains downloadable copies of this document and may also have additional background documents on irradiation, and links to other sites concerning radiation and the irradiation of products. The address (URL) of the World Wide Web site is: www.aphis.usda.gov/ppd/irrad.

You may also submit comments by postal mail. To do so, please send an original and three copies of your comments to Docket No. 95–088–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 95–046–1. Postal and e-mail comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Griffin, Senior Plant Pathologist, USDA, APHIS, PPD, 4700 River Road Unit 117, Riverdale, MD 20737–1228; (301) 734–3576; e-mail rgriffin@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Development of Policy Statement

The first draft of these positions and policies was introduced in October 1994 during the annual meeting of the North American Plant Protection Organization (NAPPO). Subsequent review has included NAPPO participants and a broadening circle of individual experts, organizations, and agencies interested in, involved in, or impacted by irradiation as a phytosanitary treatment. Numerous modifications have been made as additional information has been collected and reviewed. This document is not final or authoritative, and does not establish any agency requirements. Any requirements concerning irradiation that APHIS develops will be promulgated through rulemaking published in the Federal Register.

Since 1989, the only formally adopted regulatory policy for irradiation as a phytosanitary treatment in the United States has been based on Title 7 of the Code of Federal Regulations (7 CFR 318.13–4f, ''Administrative instructions for approving an irradiation treatment as a condition for certification of papayas for movement from Hawaii''). This authorization is specific for a commodity, place of origin, and program, but is designed for a complex of fruit flies rather than a single pest. While routine commercial shipments were never realized under this regulation due to the lack of a treatment facility in Hawaii, the authorization has proven useful from the standpoint of beginning to establish policies for irradiation as a phytosanitary treatment in the United States.

Six years later, PPQ remains dedicated to using the most up-to-date, appropriate and least intrusive technology to provide quarantine security, and the need for alternative treatments and pest mitigation systems is greater than ever. Global trade pressures and the possible loss of methyl bromide as a fumigant for regulatory pest treatments make it imperative that practical treatment options be explored.

At the same time, irradiation treatment has matured significantly. Technological advances, greater experience, and an increasingly larger body of research indicate that irradiation has important potential as a treatment for quarantine pest problems.

It is in this light that PPQ now seeks to expand the regulatory framework addressing irradiation treatment and develop comprehensive policy statements that will facilitate the development and formalization of new treatments for phytosanitary applications. This policy statement provides a sketch from which final policies can be codified after broad review and input.

Position Summary

The regulations at 7 CFR 318.13–4f provide administrative instructions for an irradiation treatment as a condition for the certification of fresh papayas

moving to the mainland States from Hawaii. These were the first regulations authorizing the use of irradiation as a quarantine treatment, and the regulations set a number of policy precedents. The regulations included the following five basic principles or policies for irradiation:

1. Requirement that irradiation facilities meet certain APHIS standards;
2. Monitoring based on inspection of treatment records and unannounced visits;
3. Policy that the Department is not responsible for damage resulting from intolerance to the prescribed dose;
4. Reliance on the authority and regulations of the United States Nuclear Regulatory Commission to ensure U.S. facilities are constructed and operated in a safe manner; and
5. Reliance on the authority and regulations of the United States Food and Drug Administration (FDA) to ensure irradiated foods are wholesome for human consumption.

The precedents described above remain valid to the extent that the same would apply to any new regulations developed by PPQ for the authorization of other treatments. However, additional clarity and completeness are necessary to address the range of commodity, pest, treatment, and operational issues potentially involved with the approval of irradiation treatments for phytosanitary problems. In addition, new information needs to be considered in adjusting existing policies, and program designs must be adapted to address the unique situations created by authorizing treatments conducted outside the United States. Therefore, in addition to the five policy precedents established by the existing regulations, APHIS has identified 28 additional policies, for a total of 33 policies relevant to irradiation.

The following are summary statements of the 28 additional policies and positions:

6. PPQ does not endorse the position that irradiation treatment should be the only replacement for methyl bromide. PPQ believes that there is adequate scientific evidence to show that irradiation provides an alternative treatment to be explored and developed, and PPQ recognizes that irradiation has potentially broad applications in the treatment of quarantine plant pests.

7. The highest priority for treatment approval is generally given to treatments deemed by PPQ to have the greatest potential immediate need, use, and benefit.

8. Treatment schedules approved by PPQ must have been demonstrated experimentally to achieve the level of efficacy required for a defined level of quarantine security.

9. To the extent possible, PPQ will ensure consistent requirements for both import and export authorizations, and align domestic requirements with foreign requirements as fairly as possible.

10. Specific authorizations for the use of irradiation as a phytosanitary treatment will initially be provided by PPQ on a case by case basis following a pest risk analysis, the evaluation of efficacy data, and the approval of operational protocols.

11. Irradiation may be used as a single treatment achieving quarantine security, or as part of a multiple treatment, or as a component in a pest mitigation system (systems approach).

12. Measures aimed at reducing pest presence prior to treatment are encouraged but will not be required for treatments achieving quarantine security. However, a very low initial infestation rate is important for enhancing the acceptance and use of irradiation as a treatment and for alleviating regulatory concerns arising from the detection of living pests in the irradiated product.

13. In those instances where pest organisms survive treatment, it is essential for quarantine purposes that the organism is unable to reproduce, and it is desirable for the organism to be unable to emerge from the commodity unless it can be easily distinguished from a non-irradiated pest of the same species.

14. Live stages of pest organisms, or their signs or symptoms, found in a commodity following a PPQ prescribed and approved irradiation treatment will be presumed by PPQ to have been effectively treated unless evidence exists to indicate that the integrity of the treatment was inadequate. PPQ may perform or require laboratory or other analyses on surviving pest organisms, or employ any available technology to verify efficacy. Authorizations may be suspended or modified and the requirements for system integrity may be adjusted based upon the results of such studies.

15. Ionizing energy (radiation) may be provided by radionuclides (gamma rays from cobalt-60 or cesium-137), electrons generated from machine sources, or by x-rays. PPQ is not concerned with specifically describing the requirements for equipment except to the extent that equipment used for plant quarantine treatments is capable of irradiating commodities to the specifications required for approved treatments.

16. Irradiation treatment must be carried out to ensure that the minimum absorbed dose (Dmin) required to assure quarantine security is fully attained throughout the commodity. The schedule process for Dmin must account for uncertainty associated with the dosimetry system employed.

17. Definition of the lower dose limit is essential to the approval of irradiation treatments for quarantine purposes. Definition of the upper dose limit is not critical to determining quarantine security, but is important from a quality standpoint and to identify potential problems with the FDA limit for the maximum dose for food (currently 1 kilogray - see 21 CFR 179.26). PPQ will not be concerned with defining the upper dose limit except to the extent that it is necessary to determine the feasibility of a particular treatment.

18. Treatments must be proven with adequate dosimetry in accordance with relevant internationally accepted standards, such as those published by the American Society for Testing and Materials (ASTM) or similar organizations. The dosimetry systems must be completely described, including records related to identifying specific suppliers, batches, processing dates, locations, and procedures as well as the means of calibration (reference dosimetry) used.

19. PPQ will confer with the Agricultural Research Service (ARS), United States Department of Agriculture (USDA) concerning the adequacy of treatment data, research protocols, and treatment design. ARS will identify or concur with the minimum dose for efficacy at the level defined by PPQ as providing quarantine security for a pest or complex of pests. Other experts may also be asked to provide input.

20. Dosages may be generic relative to a pest group or to a commodity.

21. PPQ may prescribe treatments with doses higher than what is indicated as effective by available data. This will be done to expedite the incorporation of new treatments while providing a measure of safety when PPQ and ARS judge the data to be inconclusive to the extent necessary for approving a less rigorous treatment. All treatments will be subject to amendment as new information is evaluated. PPQ expects that modifications to an existing treatment will be more easily and quickly accomplished than approval of a new treatment.

22. An irradiation program protocol, describing the details of a program surrounding a specific commodity treatment and facility processes (import or export, domestic or foreign), will be developed prior to the approval of a new facility or a new commodity for an existing facility.

23. 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.

24. Treatment facilities will be subject to the prior approval of PPQ and will be subject to periodic unannounced monitoring. Recertification by PPQ will be done on an annual basis or following repairs, modifications, or adjustments in equipment affecting the delivery of treatments. Source replenishment (in the case of radionuclide facilities) will require additional dose mapping.

25. 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 PPQ approval of a facility. Dose mapping must be performed in accordance with relevant internationally accepted standards such as those published by ASTM or similar organizations.

26. The irradiation treatment can be applied as an integral part of packing operations, or it may be done at a central location such as the port of embarkation after packing or packaging. Treatment may also be performed at the port of arrival or a designated location in the destination country when safeguards are deemed by PPQ to be adequate and operationally feasible.

27. The irradiation treatment may be applied to bulk or continuous unpackaged commodities, or the commodities may be packaged at the time of treatment. If unpackaged or exposed in packaging,[1] commodities will require safeguarding immediately following treatment to ensure that they do not become reinfested or contaminated after treatment.

28. Treated and untreated commodities must be adequately segregated and handled under conditions that will safeguard against cross-infestation or mistaken identity. Appropriate procedures specific to each facility and commodity treatment program must be approved by PPQ in advance.

29. Direct PPQ supervision of treatment programs may not be necessary for programs deemed by PPQ to provide adequate system integrity. Minimum criteria include PPQ approval of the treatment facility, National Plant Protection Organization (NPPO) certification of treatments, and PPQ approval of a program protocol for system integrity. PPQ will directly and routinely verify the adequacy of treatment facilities. PPQ presence may also be necessary for the monitoring of related program activities and system integrity.

30. Requirements for program protocols and system integrity will be harmonized with FDA, the USDA Food Safety Inspection Service (FSIS), and other regulatory authorities to the extent possible.

31. Phytosanitary certificates issued in accordance with the International Plant Protection Convention (IPPC) may be used as official documentation verifying the successful completion of a treatment. Certificates must specifically identify the treated lot and record the prescribed minimum dose and the verified minimum dose. The maximum dose may also be required in order to comply with FDA requirements for some commodities.

32. PPQ is committed to harmonizing with other U.S. agencies, States, foreign counterparts, and regulatory bodies involved with the development, approval, and application of irradiation treatments for phytosanitary problems. PPQ will make every attempt to avoid overlap, conflict, and ambiguity associated with the relationship of PPQ regulations to those of other authorities.

33. PPQ is committed to increasing its own depth of understanding concerning irradiation as a treatment for phytosanitary problems and expanding its expertise for the approval of treatments and the certification of facilities.

Research Protocols

General PPQ Requirements for the Acceptance of Irradiation as a Quarantine Treatment

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. The research necessary to demonstrate efficacy for PPQ begins 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.

Unlike most other PPQ treatment approvals, irradiation treatments may not always require a second level of confirmatory testing to demonstrate that the treatment is efficacious under the conditions associated with the commercial treatment of the commodity. However, the equipment, processes, and dosimetry for any specific treatment facility must be approved and monitored by PPQ to ensure that commercial treatments comply with the parameters for approved treatments.

Judging the feasibility of treatments for commercial applications is outside the scope of PPQ's authority and responsibility. Likewise, concerns related to phytotoxicity and issues of quality are not the responsibility of PPQ. Therefore, primary responsibility falls upon the research and commercial sectors to ensure that treatments demonstrated to be efficacious against pests of quarantine concern are also practical for commercial use.

The efficacy of the treatment as demonstrated against naked pests in vitro is the primary criterion for approval in most cases,[2] but concurrent phytotoxicity studies are important and appropriate in order to determine the commercial feasibility of proposed treatments even though data of this nature will not normally be required by PPQ to demonstrate efficacy.

General Research Protocol

If Unknown, Determine the Pest or Pests That Are of Quarantine Significance and Would be Expected to be Found on or Within the Commodity at the Time of Export

Submit this information to PPQ for concurrence. PPQ will assess the risks associated with any quarantine significant pest or pests. Irradiation may serve as the means of mitigating the risks identified in the risk analysis process.

Determine the Most Tolerant Life-stage of the Pest(s) of Concern That Would be Encountered at the Time of Treatment

If not documented in the literature, this must be determined through research. Research to determine the most tolerant life-stage may be done with naked organisms outside the commodity. Submit this information to PPQ for concurrence.

Determine the Minimum Absorbed Dosage (Dmin) and the Type of Radiation Required to Maintain Quarantine Security

Experimental design must utilize sampling methods and sample sizes appropriate for statistical tests to be used. In some instances, efficacy may be

[1] Note: Packaging materials may require FDA approval.

[2] The FDA establishes the maximum absorbed ionizing radiation dose for food (currently established at 1 kilogray for the disinfestation of food for arthropods—21 CFR 179.26). Irradiation treatments designed for the treatment of other than arthropods *in food* must receive FDA approval as well.

inferred from the literature for related species and commodities when complete laboratory investigations are not possible.[3] The means of calibration (reference dosimetry) must be described in detail and should be developed in accordance with relevant accepted standards, such as those published by ASTM or similar organizations. Submit the proposed experimental design to PPQ for concurrence.

Confirm That the Proposed Irradiation Dosage Will Provide Quarantine Security by Testing Large Numbers of Organisms

Submit the proposed experimental design to PPQ for concurrence. Analyze data statistically.

Analyze data statistically

Submit the proposed statistical methodology to PPQ for concurrence.

Describe Specific Conditions Necessary for Commercial Application of the Proposed Treatment Methodology. Specify Maximum and Minimum Absorbed Dose

Submit proposed treatment regime and conditions necessary for commercial-scale treatment to PPQ for review. This does not mean that commercial-scale testing is necessary, only that the conditions for commercial-scale treatments be described to PPQ prior to building a facility or configuring existing facilities for quarantine treatments. This provides PPQ the opportunity to address components of design, monitoring, safeguarding, and commodity handling that will be essential for the ultimate approval of a specific facility.

Specific Research Protocol: Quarantine Significant Fruit Flies

Quarantine security for a single treatment protocol will be defined as the prevention of adult emergence at the 99.9968 percent level with 95 percent confidence as demonstrated by a valid statistical method.

Specific Research Protocol: Quarantine Significant External Feeders, Hitchhikers, and Surface Contaminants

Quarantine security for a single treatment protocol will be defined as achieving 99.9968 percent sterility or mortality at the 95 percent confidence level, depending on the pest. Large scale or commercial confirmatory testing may be waived if satisfactory evidence can be presented showing that conditions in small scale testing are representative of commercial practices.

Specific Research Protocol: Quarantine Significant Systemic Organisms

Quarantine security for a single treatment protocol will be defined as achieving 99.9968 percent sterility or mortality[4] at the 95 percent confidence level, depending on the pest. Efficacy must be demonstrated with lab scale testing of organisms in host material.

System Integrity (Quality Assurance/ Quality Control)

Post-treatment safeguard methods are critical for irradiation treatments, as they are for many other commodity treatments, because the pest may continue to live and develop following treatment. As a result, confidence in the adequacy of irradiation treatment rests with the assurance that the treatment:

(a) Is efficacious against the pest under specific conditions, and

(b) Has been properly conducted and the commodity safeguarded.

To ensure condition (a) is met, strict research protocols and dosimetry requirements prevent lack of efficacy that would lead to treatment failure. Condition (b) is assured by well designed and closely monitored systems for treatment delivery and safeguards that assure system integrity.

This section addresses the policies being considered by PPQ for ensuring system integrity in the application of irradiation to phytosanitary problems. The focus of these policies is the achievement of quarantine security. Product quality is a commercial responsibility that must also be considered.

A. Pretreatment Conditions

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

Untreated commodities and other agricultural products must be stored separately from treated commodities and appropriately marked. A fail-safe means of moving the commodity from receiving areas to treatment areas in a timely fashion and without mistaken identity or risk of cross-contamination is essential.

Packaging prior to irradiation is desirable to prevent reinfestation if irradiation is done at the export source, and to prevent the accidental escape of target pests at the destination if the treatment is applied at the destination.

B. Treatment Conditions

An accurate measure of absorbed dose is critical to determining and monitoring adequacy. The required number and frequency of these measurements will be prescribed by PPQ based on the specific equipment, processes, configurations, and commodities.

Approved, standardized dosimetry must demonstrate that the absorbed dose range, including areas of the minimum and maximum dose is well mapped, controlled, and recorded for specific pests, commodities, and equipment.

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.

Absorbed dose must be measured using calibrated dosimeters approved in advance by PPQ. Dosimeters must be calibrated to a recognized national or international standard.

The number of dosimeters used shall be in accordance with relevant internationally accepted standards, such as those published by ASTM.

Complete dosimetry records must be kept by the treatment facility for at least 1 year after treatment. These records must be available to PPQ for review at any time.

Facilities and control procedures must have approval and licensing in conformance with local, national, and, where applicable, international regulatory bodies having authority over the particular situation or location. For non-U.S. locations, PPQ must judge these to be adequate and equivalent to U.S. standards.

Facilities must be certified by PPQ for use initially and at least annually. An increase or decrease in radioisotope or major modification to equipment that impacts the delivered dose must be reviewed by PPQ prior to recertification. Approval will be based on a common set of criteria plus those specific to the site and commodity programs. Significant variance in dose delivery (based on PPQ monitoring of dosimetry

[3] Quarantine security may be defined in terms of mortality or in terms of other criteria that would ensure that survivors are not able to reproduce and are not confused with untreated pests encountered inside and outside the commodity. In the case of fruit flies, PPQ has established the criterion as ''the non-emergence of adults,'' referring to interruption of the developmental sequence leading to an adult that can emerge from the commodity.

[4] Note: In general, sterility is more acceptable for organisms that remain in (or on) the host. Demonstrating the efficacy of treating organisms for sterility may be difficult to accomplish without full information on the factors favoring successful reproduction.

records) may provide the basis for requiring recertification.

Products not treated according to required schedules must be removed and discarded or otherwise eliminated from shipments for export. Retreatment is not allowed unless it can be demonstrated that there is a high degree of confidence that retreatment will not result in misidentification or cross-contamination, or conflict with other restrictions.

C. Post-treatment Conditions

Treated commodities must be protected from reinfestation by pest-proof packaging or other safeguards if treated outside the U.S.

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).

D. Documentation and Monitoring

A phytosanitary certificate will be accepted as certification of treatment. Minimum information to provide includes identification of the shipment by treatment lot and certification of the target minimum dose and the verified minimum absorbed dose.

The treatment operator must have reliable and probative evidence of correct treatment for each lot certified.

Regulatory Framework

Existing Regulations

Few PPQ treatments are specifically described within the Code of Federal Regulations (CFR). Most approved treatments are included in the PPQ Treatment Manual, which is incorporated into the CFR by reference.

An irradiation treatment for papayas from Hawaii is the only irradiation treatment currently approved by PPQ. This authorization is specific for a commodity, origin, and program but is designed for a complex of fruit flies rather than a single pest. The authorization has proven useful from the standpoint of beginning to establish policies for irradiation as a phytosanitary treatment in the United States.

Proposed Processes and Structure for New Regulations

The degree of sophisticated work and testing needed to develop and prove an irradiation treatment program make it essential that the criteria for approval be clearly understood in advance. A specific and comprehensive statement of policies combined with a pre-defined strategy for regulatory incorporation are essential to ensuring that the development and implementation of new treatments is not unduly stifled by regulatory requirements nor too liberal as to allow failures.

PPQ assumes that many additional requests for treatment approvals will be specific for pest-commodity-origin combinations and will include unique provisions for particular program parameters. Single pest treatments as well as broader targets, such as entire groups of pests, are likely to be explored. A number of individual authorizations corresponding to items within regulated commodity groups (such as fruits and vegetables or logs and lumber) will be necessary. There is also the potential for broad spectrum uses resulting in authorizations that cross the lines of existing regulated commodity groups. There is a need to provide general statements of policy and background requirements that pertain to all irradiation treatments. Any requirements concerning irradiation that APHIS develops will be promulgated through rulemaking published in the Federal Register.

The following is offered as a regulatory framework and policy communication strategy for irradiation treatment:

- Use draft position documents to solicit input in the development of policies and the collection of pertinent information.
- Use Federal Register publication and other methods to widely circulate policy statements.
- Use notice and comment rulemaking to propose and ultimately codify new treatments approved by PPQ.
- Commodity specific treatments may be incorporated through additions to the regulations specific to the commodity group (i.e., fruits and vegetables).
- Treatments with broader applications (either crossing the lines of regulated groups, or having broad spectrum pest effectiveness) may be incorporated into the CFR without being associated with an existing regulated group.

Needs and Unresolved Issues

There is a need to develop standards for conducting and reporting the findings of irradiation efficacy research for quarantine decision making, including:

—Confirmatory testing requirements with sufficient numbers to demonstrate quarantine security
—Standardized dosimetry and details concerning the methods used
—Information concerning the condition or viability of test organisms and survivors
—Information concerning the condition of the commodity before and after treatment
—Appropriate number of replications
—Appropriate methods of statistical analysis
—Criteria for combining data for different organisms or species
—Criteria for the substitution of organisms

There is a need for additional research on product tolerance, in order to:

—Establish tolerance ranges for more commodities
—Characterize treatment variables that affect phytotoxicity

There is a need for additional research on the efficacy of irradiation for other pests and diseases, including:

—Data supporting generic doses for commodity and pest groups
—Treatments for other arthropods, diseases, nematodes, noxious weeds
—Coordination with other quarantine and food safety concerns, i.e., animal products

Research is needed to develop methods to verify the adequacy of treatments, particularly a means for verifying that a live pest that has survived treatment has been adequately irradiated. This also requires development of dosimeters appropriate to the relatively low levels of irradiation used for quarantine treatments.

Research is needed to determine the conditions under which *in vitro* efficacy data can be considered acceptable in lieu of *in vivo* or *in situ* data.

There is a need to increase the number of facilities available for treatment research.

A coordinated system is needed for storing and accessing data associated with irradiation treatments for quarantine purposes.

There is a need for integration and coordination with food safety and other authorities involved in regulatory aspects of applying irradiation to agricultural commodities.

There is a need to identify critical control points for purposes of avoiding hazards (process failures) associated with treatment.

There is a need to determine the load required to have statistically meaningful results.

Finally, there is a need to develop estimates of the influence of climate or other environmental effects on the pest's susceptibility to irradiation treatment.

Current Initiatives

1. Generic Doses for Fruit Flies

An exhaustive review of the scientific literature concerning the efficacy of irradiation treatments for fruit flies in fresh fruits and vegetables has been conducted by ARS with the goal of determining whether generic dosages could be recommended. An evaluation of the results by ARS and PPQ provided the basis for the commodity-generic dosages listed below.

Tephritid species	Common name	Min. absorbed dose (Gy)
Bactrocera dorsalis[5]	Oriental fruit fly	250
Ceratitis capitata	Mediterranean fruit fly	225
Bactrocera cucurbitae	Melon fly	210
Anastrepha suspensa	Caribbean fruit fly	150
Anastrepha ludens	Mexican fruit fly	150
Anastrepha obliqua	West Indian fruit fly	150
Anastrepha serpentina	Sapote fruit fly	150
Bactrocera tryoni	Queensland fruit fly	150
Bactrocera jarvisi	(No common name)	150

[5] Unless noted as *Bactrocera dorsalis* complex, *B. dorsalis* refers specifically to the species as described by R.A.I. Drew and D.L. Hancock (1994) ''The *Bactrocera dorsalis* complex of fruit flies (Diptera: Tephritidae: Dacinae) in Asia.'' Bulletin of Entomological Research: Supplemental Series Number 2 in Supplement 2. CAB International, pp 68.

These dosages are generic in the sense that the prescribed dose is deemed appropriate regardless of the commodity. In cases where more than one of the listed species is of concern, the prescribed dose would be the dose for the most tolerant species. All doses are subject to adjustment based on the scientific evidence supporting a different dose.

2. Modification of 7 CFR 318.13–4f (Papaya From Hawaii)

The regulations at 7 CFR 318.13–4f have not been used for routine commercial shipments due to the lack of a treatment facility in Hawaii. Recently however, PPQ has been approached concerning the potential for modifying the existing regulations to allow for shipping to northern areas of the mainland U.S. for treatment, and to include tropical fruits such as lychee, rambutan, carambola, and cherimoya under a modification of the existing authorization for papaya.

Pest risk analyses have been done or are underway to determine if quarantine significant pests other than fruit flies are associated with other tropical fruits of interest. At the same time, PPQ has authorized a few experimental shipments from Hawaii to Chicago for treatment at the dose prescribed in the existing regulations.

Test shipments were authorized under strict safeguards and supervision. Each shipment was designed to provide PPQ with information and experience required to determine whether suitable program protocols could be developed and what conditions would be most appropriate. The results may provide sufficient basis for proposing modifications to the existing regulation.

3. Universal Treatment for Logs, Lumber and Unmanufactured Wood Products

Interest is high in exploring the potential to use irradiation as a means to address phytosanitary problems in raw wood products. Logs from Russia are the primary commercial focus at this time.

Russian researchers have conducted research and provided data in support of adopting a generic dose for treating raw logs. PPQ has formed a science panel consisting of scientists from APHIS, ARS, and the Forest Service to establish a research protocol, review data, and oversee the research effort toward a generic dose providing probit 9 mortality for all organisms of concern in logs from Russia. If approved, the treatment will be included among the universal treatment options in 7 CFR 319.40.

Definitions

Absorbed Dose

Quantity of radiation energy imparted per unit of mass of a specified material (D=de/dm). The mathematical relationship is the quotient of de by dm, where de is the mean energy imparted by ionizing radiation to matter of mass dm. 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.

Absorbed-Dose Rate

The absorbed dose in a material per incremental time interval, ie. the quotient of dD by dt (D=dD/dt). The unit for absorbed-dose rate is gray per second (Gy/s)

Dmax

The maximum absorbed dose within the process load.

Dmin

The 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 effect on pests.

Fruit Flies

Quarantine significant species of Tephritidae.

Gray (Gy)

Unit of absorbed dose where 1 Gy is equivalent to the absorption of 1 joule per kilogram.

1 Gy = 1 J/kg

Formerly, the special unit for absorbed dose was the rad 1 rad = .01 J/kg = .01 Gy*Ionizing radiation.*

Any type of radiation consisting of charged particles or uncharged particles, or both, 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 in commercial irradiation come from radioactive cobalt-60 (^{60}Co) or cesium-137 (^{137}Cs). X-rays (technically referred to as bremsstrahlung) are obtained using high energy electrons from an electron accelerator striking 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: as of 1994, no such devices that have the properties of a dosimeter are commercially available for the 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 standard (or some identifiable and accepted standard) to a specified uncertainty.

Pest (Plant)

Any biotic agent capable of causing damage to plants or plant products.

Phytosanitary Treatment

Subjecting or exposing a plant or plant product to a process, action, chemical or a physical influence proved to have a measurable deleterious effect on pest organisms.

Probit 9 (Mortality)

A statistical estimation of 99.99683 percent mortality in a population of live organisms, corresponding to a survival rate of 32 individuals per million.

Process Load

A volume of material with a specified loading configuration irradiated as a single entity.

Quarantine Security

A management decision concerning the safety of a defined level of pest risk. Additional mitigation is not required when quarantine security is achieved.

Rad (rad or Radiation Absorbed Dose)

Special unit for absorbed dose that is being superseded by the gray (Gy)

1 rad = 0.01 J/kg = 0.01 Gy

1 kilorad (krad) = 10 J/kg = 10 Gy

1 megarad (Mrad) = 1,000 J/kg = 1,000 Gy = 10 kGy

1Gy = 100 rads

1 kilogray = 100,000 rads

Radiation-Sensitive Indicators

Materials such as coated or impregnated adhesive-backed substrates, inks, or coatings that may be affixed to, or printed on the irradiation container and that undergo a visual change when exposed to ionizing radiation. These indicators, sometimes referred to as go/no-go indicators, are not dosimeters and are not a substitute for proper dosimetry.

Systems Approach

A combination of multiple safeguards, treatments or other mitigation measures. At least two mitigation measures must act independently to reduce risk.

Validation

Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product (quarantine security) meeting its predetermined specifications and quality characteristics.

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167, 450, 2803, and 2809; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, 371.2(c).

Done in Washington, DC, this 8th day of May 1996.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–12185 Filed 5–14–96; 8:45 am]

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FEDERAL RESERVE SYSTEM

12 CFR Part 211

[Regulation K; Docket No. R–0911]

International Banking Operations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: This final rule amends the provisions of Regulation K regarding interstate banking operations of foreign banking organizations. The Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994 (Interstate Act) removed geographic restrictions on interstate banking by foreign banks effective September 29, 1995, and requires certain foreign banks without U.S. deposit-taking offices to select a home state for the first time. The final rule requires these foreign banks to select a home state by June 30, 1996, and removes outdated restrictions on certain mergers by U.S. bank subsidiaries of foreign banks outside the home state of the foreign bank. Obsolete and superseded provisions of Regulation K concerning home state selection also are deleted.

EFFECTIVE DATE: May 9, 1996.

FOR FURTHER INFORMATION CONTACT: Ann E. Misback, Managing Senior Counsel (202/452–3788), Douglas M. Ely, Senior Attorney (202/452–5289), Andres L. Navarrete, Attorney (202/452–2300), Legal Division; Michael G. Martinson, Assistant Director (202/452–3640), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For users of Telecommunication Device for the Deaf [TDD] *only,* please contact Dorothea Thompson (202/452–3544), Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, D.C. 20551.

SUPPLEMENTARY INFORMATION:

The Interstate Act amended section 5 of the International Banking Act of 1978 (IBA), which governs interstate banking and branching operations of foreign banks. The Interstate Act also amended the Bank Holding Company Act of 1956 (BHC Act), the Federal Deposit Insurance Act and several other statutes regarding interstate banking operations of bank holding companies, national banks and state banks. In order to implement certain of these changes, the final rule amends the provisions of Regulation K regarding interstate banking operations of foreign banking organizations (12 CFR 211.22).

On December 26, 1995, the Board of Governors of the Federal Reserve