Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 305 and 319

[Docket No. 98–030–1]

RIN 0579–AA97

Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to establish regulations providing for use of irradiation as a phytosanitary treatment for fruits and vegetables imported into the United States. The irradiation treatment would provide protection against fruit flies and the mango seed weevil. This proposal would provide an alternative to the currently approved treatments (various fumigation, cold, and heat treatments, and systems approaches employing techniques such as greenhouse growing) against fruit flies and the mango seed weevil in fruits and vegetables.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by July 25, 2000.

ADDRESSES: To submit a comment by postal mail, please send your comment and three copies to Docket No. 98–030–1, 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. 98–030–1.

You may also file comments on this docket electronically, and review comments filed electronically, at the World Wide Web site http://comments.aphis.usda.gov.

You may read any comments that we receive by postal mail in our reading room. The reading room is located in room 1141 of the USDA 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: For general program and phytosanitary issues, contact Donna L. West, Import Specialist, Phytosanitary Issues Management, PPQ, APHIS, 4700 River Road Unit 140, Riverdale MD 20737–1236; (301) 734–6799. For technical irradiation issues, contact Dr. Arnold Foudin, Assistant Director, Scientific Services, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1237; (301) 734–7710.

SUPPLEMENTARY INFORMATION:

Background

I. Introduction

The Animal and Plant Health Inspection Service (APHIS) is aware of growing commercial interest in the use of irradiation as a treatment for agricultural products, both for food safety purposes (to kill pathogens and retard spoilage) and for phytosanitary purposes (to destroy plant pests). At least 38 countries have approved irradiation treatment of more than 40 foods or groups of related foods. In Europe more than 28 billion pounds of food are irradiated annually. With regard to phytosanitary irradiation treatments to control plant pests, the World Health Organization, the International Plant Protection Convention, and the North American Plant Protection Organization have endorsed the technology as effective and safe.

In anticipation of requests to allow the use of irradiation in APHIS' regulatory programs, we have been developing policies for evaluating irradiation methods and have been evaluating research on the efficacy of irradiation.

To set a framework for developing APHIS' irradiation policy, we published a notice entitled ''The Application of Irradiation to Phytosanitary Problems'' in the **Federal Register** on May 15, 1996 (61 FR 24433–24439, Docket No. 95–088–1). Among other things, the notice discussed how APHIS, in collaboration with the Agricultural Research Service (ARS), would evaluate scientific research to determine the minimum irradiation doses necessary to kill or render sterile particular pests associated with particular articles. The notice emphasized that minimum dose levels are important and necessary, but that dose levels by themselves do not constitute a complete treatment schedule or an adequate regulatory framework. Treatment schedules, in addition to specifying minimum doses, may employ irradiation as a single treatment, as part of a multiple treatment, or as a component of a systems approach combined with other pest mitigation measures. The regulatory framework for employing irradiation treatments must also address system integrity or quality control issues, including methods to ensure that the irradiation is properly conducted so that the specified dose is achieved, and must address matters such as packaging or safeguarding of the treated articles to prevent reinfestation.

This proposed rule discusses these various issues and how they must be integrated to achieve effective irradiation treatments, and then proposes specific standards for an irradiation treatment for fruit flies and the mango seed weevil in imported fruits and vegetables.

II. Critical Control Points: Dose, Dosimetry, Safeguards

We have identified three critical control points in the activities involved in irradiating imported fruits and vegetables to prevent the spread of fruit flies and the mango seed weevil. These are points where errors will definitely reduce the long-term effectiveness of the treatment and where, on the other hand, correct procedure will ensure effective treatments.

The three critical control points are:

Dose: The dose of ionizing radiation, calculated in Gray, must be sufficient to

prevent adult emergence of each species of fruit fly in fruits and vegetables. Each dose is set at the lowest level that achieves this effect; the dose will not necessarily kill larvae immediately after treatment. These doses are based on research conducted by ARS and others, as discussed below.

It is important that the dose be set at the lowest effective level for regulatory, economic, and product quality reasons. The Food and Drug Administration has issued regulations providing that fruits and vegetables may receive up to 1 kiloGray (=1,000 Gray) of irradiation (21 CFR 179.26). This current limit of 1 kiloGray for fruits and vegetables is significant because industry irradiation methods can only ensure that all articles in an irradiated lot receive a guaranteed minimum dose, at the cost of having some articles in the lot subjected to two or three times the minimum dose. Therefore, to achieve a minimum absorbed dose of 250 Gray, some articles in a lot may be subjected to a dose of 750 Gray or more. Obviously, this encourages us to set the dose at the minimum effective level to avoid the possibility of any articles being subjected to a dose above 1 kiloGray. Also, the higher the dose, the greater the cost of the irradiation treatment. Finally, irradiation causes many fruits and vegetables to suffer changes in color and texture that increase at higher doses.

Dosimetry: If *establishing* the required dose correctly is the first critical control point, *delivering* the expected dose accurately and consistently is the second critical control point. Accurate dosimetry ensures that this happens. An effective dosimetry system is necessary to ensure that irradiated articles do in fact receive the minimum required dose of ionizing radiation. An inaccurate dosimetry system that records received doses as higher than they actually are could allow survival of fruit flies or mango seed weevils in treated articles. An inaccurate dosimetry system that records received doses as lower than they actually are could result in doses exceeding the 1 kiloGray limit, as well as unacceptable changes in the color and texture of the fruits and vegetables.

Safeguards: The third critical control point, safeguards, addresses the movement and identification of articles before and after they are irradiated. There is always a risk that treated articles may become reinfested with pests after treatment, and safeguards are necessary to control this risk. If the fruits and vegetables are irradiated after arriving in the United States, safeguards must also be employed to ensure that pests do not escape from articles en route through the United States to the irradiation facility. Finally, internal safeguards, such as recordkeeping, labeling, and monitoring and enforcement of regulatory requirements, are necessary to ensure that articles are not accidentally or intentionally presented as properly irradiated when they have not been.

III. Irradiation Doses To Control Fruit Flies and Seed Weevils in Imported Fruits and Vegetables

APHIS is now prepared to propose regulations providing for the use of irradiation as a phytosanitary treatment to control 11 species of fruit flies and one species of seed weevil in imported fruits and vegetables. Based on evaluation of research that is summarized in documents available upon request,[1] APHIS is proposing irradiation for each species as follows:

FRUIT FLIES AND SEED WEEVILS IN IMPORTED FRUITS AND VEGETABLES

Scientific name	Common name	Dose (gray)
Bactrocera dorsalis	Oriental fruit fly	250
Ceratitis capitata	Mediterranean fruit fly	225
Bactrocera cucurbitae	Melon fly	210
Anastrepha fraterculus	South American fruit fly	150
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
Bactrocera latifrons	Malaysian fruit fly	150
Cryptorhynchus mangiferae	Mango seed weevil	100

ARS recommended these doses based on review of available literature, participation in workshops and meetings, discussions among ARS scientists, and verbal and written comments from numerous stakeholders and interested parties.

The recommended doses are sufficient to ensure probit 9 efficacy (a statistical estimation of 99.99683 percent mortality or sterility, corresponding to a survival rate of 32 fertile flies or weevils per million). The doses will almost entirely prevent emergence of live adults from irradiated fruits and vegetables.

ARS found sufficient data in its review of research[2] to recommend irradiation doses for 11 species of tephritid fruit flies and one species of seed weevil.

In 1986, minimum doses of 150 and 300 Gray were internationally proposed for quarantine security of tephritid fruit flies and all other arthropods, respectively (Loaharanu 1992). It was concluded that the dose of 150 Gray should prevent development of adult tephritid fruit flies capable of flight when eggs and larvae are irradiated, while 300 Gray should cause sterility to all stages of other insects and mites.

The first calculated estimates of doses to provide probit 9 security against fruit fly adult emergence were made by Balock *et al.* (1966). The probit 9

[1] ''Recommendation Irradiation Dose to Provide Quarantine Security for Commodities Infested with Certain Fruit Fly Species,'' Agricultural Research Service, April 7, 1995, and corollary APHIS memoranda. You may request these documents from the person identified above under **FOR FURTHER INFORMATION CONTACT,** or download them from http://www.aphis.usda.gov/ppd/irrad.

[2] Reports from many of the researchers cited in this document are available in a single compilation, ''Proceedings of the Final Research Coordination Meeting on Use of Irradiation as a Quarantine Treatment of Food and Agricultural Commodities, August 27–31 1990''; published by the International Atomic Energy Agency; U.S. distributor UNIPUB, Lanham, MD. Parties interested in irradiation research reports may also be interested in a huge bibliography on agricultural irradiation assembled by the Federal Research Center for Nutrition in Germany, and available on their Web site at http://www.dainet.de/bfe/english/thmliste.htm.

estimate of the irradiation dose that would prevent the emergence from fruit of adult Oriental fruit fly, *Bactrocera dorsalis* (Hendel), varied from 206 Gray in papaya to 280 Gray in a combination of eight different fruits. The fruits tested in this research ranged in size from Barbados cherry to tangerine and were infested with immature stages of the fruit fly ranging from egg to third instar. For melon fly, *Bactrocera cucurbitae* (Coquillett), combined data on irradiation of eggs through third instars in papaya, tomato, and cucumber gave a probit 9 estimate of 156 Gray. Two adult Mediterranean fruit flies, *Ceratitis capitata* (Wiedemann), emerged from approximately 1,300 early instar larvae in papayas treated at 100 Gray. However, the study's authors believed that these two flies resulted from post-treatment infestation because no adults emerged from papayas infested with approximately 19,000 early instars and treated with 25–75 Gray. No estimate of probit 9 security for *C. capitata* was offered. No tests using large numbers of *B. dorsalis* or *B. cucurbitae* were conducted at the estimated probit 9 doses; therefore, accuracy of these estimates was not confirmed.

Seo *et al.* (1973) subjected large numbers of fruit fly immatures inside fruits to irradiation doses ranging from 209 to 291 Gray. Doses as high as 244 Gray allowed some *B. dorsalis* to emerge as adults; it was not stated whether these adults were capable of flight. No irradiated *B. cucurbitae* immatures emerged as adults even at doses as low as 209 Gray. Two adult *C. capitata* emerged from an estimated 110,772 *C. capitata* immatures irradiated at 225 Gray. It was not mentioned whether either adult was capable of flight. Based on this study, Burditt and Seo (1971) recommended a dose of 210–250 Gray to prevent adult emergence of these three flies infesting tropical fruits in Hawaii.

Other studies dealt with irradiation of fruits infested with *B. dorsalis* and *C. capitata*. Although no adults emerged from an estimated 18,000 *B. dorsalis* third instars irradiated with 150 Gray in carambolas, emergence was less than 10 percent in the untreated control, indicating that the pupae were exposed to severe mortality factors unrelated to irradiation (Vijaysegaran *et al.* (1992)). A dose of 100 Gray prevented adult emergence of an estimated 131,148, 5- to 6-day-old *B. dorsalis* immatures irradiated in 250–300 gram ''Carabao'' mangoes (Manoto *et al.* (1992)). Komson *et al.* (1992) irradiated an estimated 173,042, 5-day-old *B. dorsalis* larvae reared at 27 (+/−2)°C in ''Nang Klangwan'' mangoes with 150 Gray with one adult survivor. Although no *C. capitata* adults emerged from an estimated 100,854 third instars in mangoes exposed to 150 Gray, 5 adults emerged from an estimated 5,268 larvae irradiated at that same dose in a previous test (Bustos *et al.* (1992)). Bustos *et al.* (1993) felt that 250 Gray was required to prevent development of adult *C. capitata* from irradiated larvae.

In Australia, various researchers have irradiated, at 50–100 Gray, a wide variety of fruits infested with large numbers of all immature stages of Queensland fruit fly, *Bactrocera tryoni* (Froggatt), with no apparently normal adult survivors. An estimated total of 566,714 ''old larvae'' were subjected to 75 Gray in five different fruits with no normal adult survivors. Heather *et al.* (1991) irradiated an estimated 110,935 eggs and 153,814 third instars of *Bactrocera jarvisi* (Tryon) in ''Kensington'' mangoes with 74–100 Gray and obtained no normal adult survivors.

Large numbers of five species of *Anastrepha* in fruits have been irradiated with doses of 50–150 Gray with no apparently normal adult survivors. However, von Windeguth (1986) found one apparently normal adult *A. suspensa* from an estimated 25,363 third instars in mangoes irradiated with 55 Gray.

Cherries infested with western cherry fruit fly, *Rhagoletis indifferens* Curran, were irradiated with a mean dose of 97 Gray, and one adult with vestigial wings emerged out of an estimated 15,812 immatures (Burditt and Hungate (1988)).

APHIS bases its proposed irradiation doses on the pertinent literature. The doses vary according to species, because the resistance of species varies. We propose to require a minimum dose of 250 Gray for *B. dorsalis* based on the study of Seo *et al.* (1973), who obtained 17 adults from a total of 490,289 larvae in papaya irradiated at a minimum dose of 244–252 Gray. At lower doses (214–225 Gray) in papaya, 5 of a total of 306,431 immatures developed to adults. Given the data of Seo *et al.* (1973), a dose of 250 Gray for *B. dorsalis* appears marginally effective at producing probit 9 security. However, it seems that the high survival rate at a dose of 244 Gray was atypical (17 adults emerged from 130,156 immature forms irradiated with 244 Gray), given that the study showed that fewer adults emerged at lower doses. No adults emerged when 155,903 immature forms in papayas were irradiated with 214 Gray. The only other large-scale studies with *B. dorsalis* used very high infestation levels and included few third instars, which may have reduced tolerance of the insects to irradiation (Komson *et al.* (1992); Manoto *et al.* (1992)).

We propose a minimum dose of 225 Gray for *C. capitata.* At 225 Gray, 2 of an estimated 110,772 *C. capitata* larvae completed development to the adult stage (Seo *et al.* (1973)). Furthermore, although no larvae of an estimated 100,854 third instar *C. capitata* in mangoes irradiated with 150 Gray became adults, the fact that 5 of 5,268 larvae did in an earlier test cannot be ignored (Bustos *et al.* (1992)).

We propose a minimum dose of 210 Gray for *B. cucurbitae* because at a dose of 209 Gray no *B. cucurbitae* larvae of an estimated 169,903 in bell peppers reached the adult stage (Seo *et al.* (1973)). The study's authors did not test lower doses, and no other studies using large numbers of *B. cucurbitae* have been conducted.

We propose a minimum dose of 150 Gray for eight other tephritid fruit flies: *B. tryoni, B. jarvisi, B. latifrons, A. fraterculus, A. suspensa, A. serpentina, A. ludens*, and *A. obliqua*. Although the research evidence shows that lower doses might suffice, a dose of 150 Gray should pose no greater problem to irradiation-tolerant commodities compared with lower doses, and it provides greater security.

We propose a minimum dose of 100 Gray for the mango seed weevil, *Cryptorhynchus mangiferae*, because research by ARS (Follett, 1999) has demonstrated that the weevils are effectively killed or sterilized at this dose.

IV. Dosimetry and Dose Control Issues

It is critical to ensure that articles actually receive the required dose during irradiation, since lower doses could allow pests to survive. Fortunately, the irradiation industry and researchers have spent decades developing and documenting effective systems for dosimetry. We are confident that facilities that correctly apply dosimetry guidance published by the American Society for Testing and Materials (ASTM) will be able to reliably measure the doses regulated articles receive.

The basic product delivered by businesses engaged in irradiation is an accurately measured dose of ionizing radiation, within the range requested by the customer, delivered to articles provided by the customer. Therefore, dosimetry is an integral part of these businesses' procedures, and APHIS does not need to address dosimetry in detail in this proposal, other than to require that the businesses follow good dosimetry practices to map, control, and record the radiation dose. Guidance and

requirements for dosimetry by ASTM, the U.S. Department of Energy, and APHIS, and supervision by responsible national agencies in foreign countries, establish the degree of dosimetry reliability needed to make this proposal work.

V. Safeguards for Different Irradiation Situations

Safeguards reduce risk by controlling the movement and identification of articles before and after they are irradiated. Safeguards include such matters as packaging, labeling, records, and irradiation facility construction and procedures. The types of safeguards needed to reduce risks will change with changing conditions. Certain safeguards are needed if the irradiation facility is located in an area infested with fruit flies, or if irradiated commodities leaving the facility en route to the United States will transit such an area where the risk is high that flies could oviposit in fruit after it is irradiated. These identical safeguards would not be needed if the irradiation takes place in an area not infested with fruit flies.

The actual safeguards needed for different situations are discussed below under ''Proposed Regulatory Framework for Irradiation Treatments.'' The goal of the safeguards is to address risks that are *not* fully addressed by the technical irradiation components of this proposal. Such risks include misidentification of articles so that untreated cartons are delivered labeled as treated, reinfestation of treated articles after treatment, and escape of fruit flies from articles in the United States prior to treatment.

Most of the safeguards we are proposing are based on previous operational experience that shows these safeguards to be effective when required to import fruits and vegetables that are subject to a variety of treatments under our regulations (e.g., fumigation, hot water dips, cold treatments). For instance, many existing treatments require the treated articles to be packed in insect proof cartons after treatment, and require labeling to distinguish treated from untreated cartons. The proposed safeguards concerning the allowed locations of irradiation facilities in the United States, and the routes untreated articles may follow to these facilities, are based on operational experience showing that the pests of concern cannot become established in the climate prevailing in the States where irradiation facilities would be allowed. The safeguards concerning records that irradiation facilities would have to keep (concerning lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation) are based on procedures the irradiation industry has endorsed and found effective in documenting that various irradiated articles (e.g., medical supplies) receive the required dose of irradiation.

VI. Proposed Regulatory Framework for Irradiation Treatments

As discussed above, we have proposed, based on research data, the doses of radiation for imported fruits and vegetables that effectively prevent the emergence of living adult forms of 11 species of fruit flies and one species of seed weevil. The above discussion also explains how we propose to measure and verify delivery of the effective doses and that safeguards may be needed to prevent pest escape from products before treatment and reinfestation after treatment. These elements of irradiation treatment fit into the existing APHIS regulatory structure as follows.

First, we propose to establish a new part 305 in title 7 of the Code of Federal Regulations. The new part 305 would be titled ''Phytosanitary Treatments.'' At this time, this part would contain only the irradiation treatment schedules and procedures for treatment for 11 species of fruit flies and one species of seed weevil in fruits and vegetables. In the future, APHIS may add more of its existing and new treatments to part 305 to make it easier for customers to find treatments and to simplify cross-references in our regulations.

In addition to establishing a new part 305 to contain the irradiation treatment schedules, we also propose to make changes to ''Subpart—Fruits and Vegetables'' (7 CFR 319.56 through 319.56–8) to authorize the importation of articles irradiated in accordance with the new part 305.

New part 305 would also specify requirements for irradiation facilities performing the irradiation. These requirements would include procedures for approving the facility, monitoring facility operations, recordkeeping, dosimetry, and packaging of fruits and vegetables treated at the facility. These requirements in the new part 305 would be similar to existing APHIS regulations concerning irradiation treatments. These include regulations for moving regulated articles interstate from Mediterranean fruit fly quarantined areas (7 CFR 301.78–10), and regulations for moving certain fruits and vegetables interstate from Hawaii (7 CFR 318.13–4f).

Proposed § 305.1 would set forth definitions of the terms *Administrator, APHIS, Dose mapping, Dosimetry,* and *Dosimetry system.* The first two terms would use the same definitions commonly in use in other APHIS regulations. The final three terms would use definitions consistent with accepted nuclear industry use of those terms.

Proposed § 305.2(a) would set forth the common and scientific names of the fruit flies and seed weevil for which irradiation treatment is authorized and the dose in Gray required for each species.

Proposed § 305.2(b) would allow irradiation to be conducted prior to the arrival of articles in the United States, or after arrival, but would limit the location of facilities in the United States to certain northern States where the climate would preclude the successful establishment of the targeted fruit flies, *i.e.,* any State on the mainland United States except Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, and Virginia. We propose this location restriction as a safeguard against the possibility that, despite container and movement restrictions designed to prevent this possibility, fruit flies could escape from regulated articles in the United States prior to treatment. Paragraph (b) also would provide that fruits and vegetables to be irradiated may not move into or through the States listed above prior to treatment, except that Dallas/Fort Worth, TX, would be an authorized stop for air cargo or a transloading location for shipments that arrive by air but that are subsequently transloaded into trucks for overland movement from Dallas/Fort Worth into an authorized State by the shortest route. Dallas/Fort Worth would be an exception because the transloading facility at the airport is under USDA supervision, and both the facility procedures and the climate and host material in the immediate area minimize the risk that fruit flies could escape and become established.

This geographic restriction of irradiation facilities to States where fruit flies would not survive the winter may be reevaluated later if evidence from irradiation operations shows the risk of fruit fly escape and spread from the facilities to be insignificant.

Proposed § 305.2(c) and (d) would require that facilities conducting authorized irradiation treatments, and importers moving articles to such facilities in the United States, must do so under a compliance agreement with APHIS.

Proposed § 305.2(e) would require that facilities conducting irradiation treatments be certified by the Administrator of APHIS. Certification would not expire after a fixed time; however, a facility would have to be recertified after an increase or decrease in radioisotope, natural deterioration of the radioisotope, a major modification to equipment that affects the delivered dose, or a change in the owner or manager of the facility. Recertification also may be required in cases where a significant variance in dose delivery has been measured by the dosimetry system.

In order to be certified, a facility would have to be capable of administering the minimum absorbed ionizing radiation doses and be constructed according to specified standards so that treated and untreated fruits and vegetables are kept in separate locations with a physical barrier between them to prevent the transfer of cartons. Treated and untreated fruits and vegetables could be separated with barriers such as a 6-foot wall or chain link fence to minimize interference with facility operations and visibility.

It might seem that an insect proof barrier should separate the areas for untreated and treated articles. Obviously, a chain link barrier would not prevent flies from emerging from fruits on the untreated side, flying to the treated side, and leaving the facility in fruit that has been irradiated. However, we believe an insect proof barrier in the facility is unnecessary because it is extremely unlikely that fruit and vegetable shipments, moved by air freight and irradiated on speedy industrial schedules, would be around long enough prior to treatment for fruit flies to hatch, emerge, and spread to the untreated side of the facility. Larvae and pupae, if any are present in the articles, are not mobile enough to move from untreated cartons to treated cartons. Adult flies are unlikely to be present with commercial fruit, which is usually shipped before it is fully ripe. Therefore, an insect proof barrier separating the facility areas for treated and untreated articles is not needed.

Another safeguard in proposed § 305.2(e) provides that a facility in the United States would only be approved to irradiate imported regulated articles if the Administrator determines that regulated articles would be safely transported to the facility from the port of arrival without diversion to any other destination, and without significant risk that plant pests will escape in transit or while the regulated articles are at the facility. The compliance agreement for a facility located in the United States would require the facility to comply with additional requirements to prevent escape of plant pests from the articles prior to their treatment. One of these requirements would be prompt irradiation of the fruits and vegetables to minimize the risk that fruit flies could emerge from the articles and spread to treated articles and reinfest them.

Proposed § 305.2(f) concerns monitoring of treatments. Treatment in U.S. and foreign facilities would have to be monitored by an APHIS inspector, who would also inspect treatment records and make unannounced inspections of the facility. We propose to require facilities that carry out continual irradiation operations to notify an inspector at least 24 hours before the date operations commence. Facilities that carry out periodic irradiation operations would have to notify an inspector at least 24 hours before scheduled operations.

We believe this level of monitoring is necessary to ensure that irradiation is effectively conducted. Monitoring and verification are extremely important to ensure the integrity of the entire system for irradiating imported fruits and vegetables. This is because there is no practical way for an inspector to determine, based on physical evidence from the commodity itself, that a commodity has been irradiated. Irradiation leaves no residue and usually causes no discernable change to the commodity's color or texture. In addition, an effective irradiation treatment may not kill all larvae, but instead might prevent adult emergence. In cases where an inspector at the port of arrival encounters live larvae of the target pest in a shipment that is documented as irradiated, it is extremely important that the documentation and procedures of the irradiation treatment system allow the inspector to determine with full confidence that the commodity was properly treated according to APHIS requirements.

Proposed § 305.2(g) prescribes requirements for the packaging of irradiated fruits and vegetables.

First, all irradiated fruits and vegetables must be shipped in the same cartons in which they are irradiated, and no irradiated fruits or vegetables may be shipped in the same carton with nonirradiated fruits and vegetables. This is to prevent confusion as to the treatment status of the articles.

In addition, fruits and vegetables irradiated before arrival in the United States would have to be packaged as follows:

The cartons must be insect proof unless the treated fruits and vegetables are stored in an insect proof room after irradiation and are wrapped on their pallets in insect proof polyethylene, shrink wrap, or fine netting before being shipped to the United States. If insect proof cartons are employed, they may have no openings that could allow the entry of fruit flies, and must be sealed with seals that will visually indicate if the cartons have been opened. The cartons may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the articles in the carton.

We also propose the following pallet security requirement for articles irradiated prior to arrival in the United States, regardless of whether insect proof cartons are employed. In order to ensure that no cartons are added to or removed from a pallet load of cartons containing irradiated fruits or vegetables, pallet loads would have to be wrapped in one of the following ways: With polyethylene sheet wrap, with net wrapping, or with strapping so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap.

We further propose to require that pallet loads of irradiated fruits and vegetables be marked with irradiation lot numbers, packing and irradiation facility identification and locations, and dates of packing and irradiation. If the pallet load is broken down into smaller units before or during the process of entering the United States, the individual cartons would have to be labeled with this information. This information would allow an inspector to identify the irradiation lots and trace them back to the packing and irradiation facilities. While this labeling imposes some burden on the importer, some of the information, *e.g.,* identification of the packer, is already normally required for imported fruits and vegetables, and irradiation facilities routinely label treated articles with the identity of the irradiation facility, the lot number, and the treatment date upon request. This labeling is normally done for each pallet, but other arrangements may be made if the pallet is to be broken into smaller units prior to entry into commerce in the United States. Irradiation facilities have indicated that they can work with customers to minimize the cost and inconvenience of such labeling, *e.g.,* by providing customers with preassigned lot numbers so they can be printed on the cartons along with the packer's name.

We are not proposing any special packaging requirements for articles to be irradiated in facilities in the United States. Untreated fruits and vegetables imported for irradiation in the United States may be packed in ventilated

cartons that are not insect-proof. The cartons will generally be imported in shipping containers that are not opened until they reach the facility, and importers must sign compliance agreements with APHIS that will ensure against diversion of the shipment to a destination other than treatment, and against possible releases of fruit flies en route. No additional packing requirements appear necessary because the articles are destined for irradiation facilities in States where fruit flies cannot become established and spread.

Proposed § 305.2(h) concerns dosimetry requirements. We propose to require that absorbed dose be measured at the treatment facility using a dosimetry system that can accurately measure a minimum absorbed dose of 150, 210, 225, and 250 Gray, to match the required doses for the relevant species of fruit fly. We would require that the dosimetry system, including the number and placement of dosimeters used at the facility to measure the absorbed dose, be in accordance with standards of the American Society for Testing and Materials (ASTM). (See Designation E 1261–94, ''Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing,'' American Society for Testing and Materials, *Annual Book of ASTM Standards.*)

We considered proposing to require that each carton or other container of fruits or vegetables contain a radiation indicator that is placed in the carton or other container prior to irradiation and remains in place until after the fruits and vegetables have entered the United States. Such indicators, in the form of chemically impregnated stickers that change color after exposure to specified levels of ionizing radiation, are inexpensive and are in common use on cartons of medical supplies irradiated for sterility. This requirement would assist our inspectors by providing them with a tool to determine that a particular carton has been irradiated. Using such an indicator would also be a safeguard against fraudulent representations in paperwork that articles had been irradiated when they had not.

However, we have decided not to propose such a requirement at this time, for the following reasons. There are no indicator stickers currently on the market that change color in the 150–250 Gray range proposed in this document; the medical products indicators mentioned above react in the 1 kiloGray range. Also, such indicators are not accurate dosimeters and may in fact change color when exposed to conditions other than irradiation treatment (*e.g.,* intense sunlight or temperature changes). While further developments may eventually make such indicators useful for monitoring compliance with irradiation requirements for fruits and vegetables, we do not believe they would be useful now.

Proposed § 305.2(i) would require the treatment facility to maintain records of treatment for 1 year after each lot is treated. We would require the records to include the lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation. All records would have to be available for review by APHIS inspectors during normal business hours. These detailed records are necessary to ensure system integrity for irradiation treatments and for successful enforcement of the regulations and identification of fraudulent documents or other violations. We believe that all of these records are already kept by irradiation facilities, either as normal business practice or as required by the Nuclear Regulatory Commission or State agencies.

Proposed § 305.2(j) and (k) describe how a person would request certification by APHIS of an irradiation facility, and how such certification could be denied or withdrawn by the Administrator.

Proposed § 305.2(l) states that the Department of Agriculture and its inspectors assume no responsibility for any loss or damage resulting from irradiation treatment. From the literature available, we believe the fruits and vegetables authorized for treatment under this section are tolerant to the minimum absorbed dose required by the treatment. However, the facility operator and shipper would be responsible for determination of tolerance. This paragraph also briefly describes the responsibilities of the Nuclear Regulatory Commission and the Food and Drug Administration in regulating irradiation facilities.

Damage to treated commodities is a significant issue for importers. In fact, one reason there is interest in irradiation treatments is that the treatment is effective against fruit flies in a number of tropical fruits and other articles that do not survive other treatments well; *e.g.,* papaya, rambutan, carambola, litchi. Some research has shown changes to fruit color and texture when they are irradiated at several times the required minimum dosage. This could be a problem because some irradiation facilities may subject the articles to two to three times the required minimum dose—either to ensure that all articles in a treated lot (both those nearest to and farthest from the radiation source) receive at least the required minimum dose, or because it is simply infeasible to expose the articles to the radiation source and then remove them quickly enough to achieve only the minimum required dose.

To illustrate this dose range problem, consider that, in a typical irradiation facility fruits may be treated while they are stacked in cartons on 4-by-4 foot pallets. When these stacks are exposed to the radiation source, an exposure long enough to result in the minimum required dose for the fruit in the center of the stack will result in a significantly higher dose for fruit on the outside of the stack, even if the stacks are rotated during irradiation. Also, some minimum required doses are so small that an entire stack of pallets need be exposed to the radiation source for 1 minute or less, but it is very difficult to move the stack of pallets through the irradiation chamber quickly enough to achieve only the minimum dose.

Therefore, persons using irradiation treatments on their commodities should pay close attention to the studies of effects on commodity quality of radiation doses over the level required by APHIS, and should understand the procedures employed by the irradiation facility and work with the facility to avoid doses that might negatively affect quality.

The following table [3] is presented to give some idea of the relative tolerances to irradiation of different fruits and vegetables.

IRRADIATION DOSES BELOW 1 KILOGRAY.—RELATIVE TOLERANCES OF FRUITS AND VEGETABLES

High	Apple, cherry, date, guava, longan, muskmelon, nectarine, papaya, peach, rambutan, raspberry, strawberry, tamarillo, tomato.

[3] Kader, A.A., 1986. ''Potential Applications of Ionizing Radiation in Postharvest Handling of Fresh Fruits and Vegetables,'' Food Technology, v. 40, no. 6, June 1986.

IRRADIATION DOSES BELOW 1 KILOGRAY.—RELATIVE TOLERANCES OF FRUITS AND VEGETABLES—Continued

Medium	Apricot, banana, cherimoya, fig, grapefruit, kumquat, loquat, litchi, orange, passion fruit, pear, pineapple, plum, tangelo, tangerine.
Low	Avocado, cucumber, grape, green bean, lemon, lime, olive, pepper, sapodilla, soursop, summer squash, leafy vegetables, broccoli, cauliflower.

This table should not be considered authoritative, as many variables affect radiation tolerance. For example, although grapes are considered to have low tolerance, in the past year grapes have been irradiated and moved from the Medfly-quarantined area in Florida, in accordance with § 301.78–10, without apparent effects on the quality of the fruit.

VII. Proposed Changes to the Fruits and Vegetables Import Regulations

As discussed above, in addition to establishing a new part 305 to contain the irradiation treatment requirements, this proposal would also make changes to the regulations to authorize the importation of fruits and vegetables using those treatments.

Regulations for importing fruits and vegetables are contained in ''Subpart—Fruits and Vegetables'' (7 CFR 319.56 through 319.56–8).

APHIS intends that irradiation, where available, may be substituted for, or used in conjunction with, any other treatment or special growing and handling conditions (systems approach) required by ''Subpart—Fruits and Vegetables'' or the Plant Protection and Quarantine Treatment Manual to mitigate the risk associated with any of the 11 species of fruit flies and one species of seed weevil named in this proposal. The fruits and vegetables regulations cover a large number of importation scenarios, and the requirements of the regulations depend on the risks presented by the particular article being imported. Fruits or vegetables imported from an area with no significant pests of concern may be imported without any treatment, subject only to inspection upon arrival. At the other extreme, fruits or vegetables imported from an area with several significant pests might have to undergo several different treatments to be eligible for importation.

''Subpart—Fruits and Vegetables'' contains a number of administrative instructions in §§ 319.56–2a through 319.56–2ee that specify unique combinations of treatments, procedures, and other tailored requirements to allow the safe importation of various articles. However, in recent years our policy has been to list most articles under one of two sections. Section 319.56–2t lists articles that may be imported from various foreign locations *without any required treatment,* subject to inspection and other activities at the port of arrival. Section 319.56–2x lists articles that may be imported from various foreign locations *only if they have been treated* in accordance with the Plant Protection and Quarantine (PPQ) Treatment Manual, which is incorporated into the regulations by reference at 7 CFR 300.1.

The PPQ Treatment Manual includes a number of fumigation, cold, and heat treatments to control the 11 species of fruit flies and one species of seed weevil that APHIS has determined can be controlled by irradiation of fruits and vegetables. Therefore, we propose to amend § 319.56–2x to state that the listed articles may be imported only if they have been either: (1) Treated in accordance with the PPQ Treatment Manual, or (2) treated by irradiation in accordance with 7 CFR part 305 if treatment is required by the PPQ Treatment Manual for one or more of the 11 species of fruit flies and one species of seed weevil listed in part 305.

There are also sections of ''Subpart—Fruits and Vegetables'' other than § 319.56–2x that require that some fruits and vegetables be treated or subjected to special growing and handling conditions (a systems approach) for fruit flies. For example, § 319.56–2h requires fumigation of grapes from Australia for several pests, including two fruit flies. Section 319.56–2k prescribes fumigation of grapes from many countries, and the pests of concern for this section are often fruit flies. Therefore, we also propose to add a new paragraph (k) to § 319.56–2 to allow substitution of irradiation for fruit fly treatments or systems approaches that are required by any section in ''Subpart—Fruits and Vegetables.'' New paragraph (k) would read ''Any fruit or vegetable that is required by this subpart or the Plant Protection and Quarantine Treatment Manual to be treated or subjected to other growing or inspection requirements to control one or more of the 11 species of fruit flies and one species of seed weevil listed in § 305.2(a) of this chapter as a condition of entry into the United States may instead be treated by irradiation in accordance with part 305 of this chapter.''

For example, § 319.56–2x currently allows importation of grapefruit and oranges from Mexico if they are treated in accordance with the PPQ Treatment Manual, which requires a cold treatment (T107) of these commodities for several species of fruit fly that attack grapefruit and oranges in Mexico. Because these species of fruit fly are among the 11 species listed in proposed part 305, grapefruit and oranges from Mexico could be imported subject to irradiation treatment instead of the cold treatment. Another example where irradiation treatment could be substituted would be kiwis and tangerines from Greece. Currently, the PPQ Treatment Manual requires either a cold treatment (T107(a)) or fumigation plus refrigeration (T108(a)) to control fruit flies in these articles from Greece. An example of a scenario where treatment for fruit flies is required by a different section of ''Subpart—Fruits and Vegetables'' would be grapes imported from Algeria under § 319.56–2k; if fruit flies are the only pest in that country requiring precooling and fumigation under § 319.56–2k, the grapes would be allowed to enter the United States if they receive an irradiation treatment instead. Another scenario under which the proposed irradiation treatment could be used in lieu of current regulatory requirements would be the current importation of pink or red tomatoes from Spain in accordance with § 319.56–2dd. To prevent the introduction of Mediterranean fruit fly, § 319.56–2dd imposes various requirements including greenhouse growing of the tomatoes, fruit fly trapping surveys in the greenhouse area, and shipping only during winter and early spring months. If this proposal is adopted, shippers of pink and red tomatoes from Spain could choose to irradiate them rather than meet the requirements of § 319.56–2dd.

These are examples of the simplest scenario under the present proposal, *i.e.,* importing articles when the only pests of concern are one or more of the 11 species of fruit flies. However, sometimes other pests that attack the articles will be present in the place of origin. If the regulations or the PPQ Treatment Manual require the article to be treated for these additional pests, the articles must receive any additional required treatment, in addition to irradiation for fruit flies or mango seed weevils.

The proposed irradiation doses are specific to the identified species of fruit fly or seed weevil but generic for the commodity. Any fruit or vegetable may be treated at the dose prescribed for the fruit fly of concern. The treatment for the fruit fly requiring the highest dose would be required when more than one species of fruit fly is a pest of concern.

VIII. Compliance With Executive Orders, Regulatory Flexibility Act, National Environmental Policy Act, and Paperwork Reduction Act

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

The economic analysis for the changes proposed in this document is set forth below. It provides a cost-benefit analysis as required by Executive Order 12866 and an analysis of the potential economic effects on small entities as required by the Regulatory Flexibility Act.

In accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis regarding the effect of this proposed rule on small entities. Because we do not currently have all the data necessary for a comprehensive analysis of the effects of this rule on small entities, we are inviting comments concerning potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from implementation of this proposed rule.

Under the Federal Plant Pest Act (7 U.S.C. 150aa–150jj) and the Plant Quarantine Act (7 U.S.C. 151–165 and 167), the Secretary of Agriculture is authorized to regulate the importation of plants, plant products, and other articles to prevent the introduction of injurious plant pests.

This proposed rule would permit the treatment of imported fruit and vegetables by irradiation, in place of or in conjunction with existing phytosanitary treatments or other protocols, for 11 species of fruit flies and one species of seed weevil. Irradiation could take place prior to shipment to the United States or after arrival. There would be requirements for certification of the facilities, treatment monitoring, pallet security, and recordkeeping for irradiation at all facilities, and packaging and labeling requirements for articles irradiated before arrival in the United States. Irradiation facilities would have to use an approved dosimetry system during treatment and keep records to verify effective irradiation. For irradiation after arrival, compliance agreements would impose requirements on the transit from ports to irradiation facilities, to ensure all shipments requiring irradiation are delivered to the facility and are not rerouted to sale prior to treatment.

Firms in the United States primarily affected by this proposed rule would be ones conducting the irradiation treatments. They could be variously classified by the Small Business Administration, depending on each one's particular business enterprises. A firm providing irradiation services strictly for the treatment of crops, including imported fruits and vegetables, would be included in the Standard Industry Classification (SIC) category 0723 (Crop Preparation Services, except Cotton Ginning). A firm would qualify as a small entity if it had annual revenues of $5 million or less. If a firm that imports or wholesales fruits and vegetables were to perform the irradiation itself, it would be included in SIC 5148 (Fresh Fruits and Vegetables), since its principal activity would remain importing or wholesaling. In this case, the firm would be designated as a small entity if it had 100 or fewer employees.

Firms expected to benefit most immediately from this proposed rule, however, would not belong in either of these SIC categories. They would be companies that currently provide irradiation services on contract for decontamination or sterilization purposes and could readily adapt to perform phytosanitary irradiation. They are classified within SIC 2099 (Food Preparations, N.E.C.) or SIC 2842 (Specialty Cleaning, Polishing, and Sanitation). The former category includes firms that irradiate food items, such as spices, seeds, culinary herbs, vegetable seasoning, and poultry, to destroy harmful pathogens. Included in SIC 2842 are firms that primarily provide irradiation services for the sterilization of medical devices, pharmaceutical preparations, and raw materials used in cosmetic products.

Four firms with SIC 2099 or 2842 designations have been identified that provide irradiation services on contract. For both categories, employment of 500 or fewer persons qualifies a firm as a small entity. Three of the four firms are considered small. (The fourth one had been a small entity until last year, when it was purchased by another corporation.)

Of these four companies, the one that is not a small entity is the only one engaged at present in phytosanitary irradiation. This firm treats papayas, carambolas, litchis, and other tropical fruits from Hawaii that are moved interstate to the mainland United States. Irradiation of the fruit in accordance with 7 CFR 318.13–4f, performed at facilities in Illinois, removes the risk of Mediterranean, Oriental, and melon fruit fly introduction, while also lengthening the shelf life of the fruit. Treatment of the Hawaiian fruit, however, is a small part of the firm's business; irradiation services are mainly provided for sterilization purposes through a network of facilities in nine States and Canada.

Similarly, the second of the four firms has 12 facilities throughout the United States, 8 of which are used for medical sterilizations and 4 for other purposes. One of the 12 facilities, located in southern California, has been adapted for irradiation of fruits and vegetables for the purpose of lengthening shelf life.

The other two firms that provide irradiation services are single-facility businesses. One, in Maryland, principally conducts medical and pharmaceutical sterilizations, and the other, in Florida, has been irradiating poultry products for the retail market and hospitals since 1993.

In addition to these four firms, companies that use irradiation to sterilize their own products could also benefit from this proposed rule by contracting their irradiation facilities for phytosanitary purposes. Location, throughput capacity, the irradiating processes used, and other characteristics of the facilities would help determine whether the cost of their services would be competitive in comparison to the cost of alternative methods of treatments.

While these firms are technologically capable of taking advantage of treatment opportunities afforded by this proposed rule, any economic effects on them will ultimately depend on the cost effectiveness of irradiation when compared to alternative phytosanitary treatments. A 1994 study sheds light on the benefits and costs of irradiation versus methyl bromide (MB) fumigation for the treatment of imported fruits and vegetables.[4] Economic benefits in this study were estimated in terms of preventing potential economic losses in U.S. fruit and vegetable markets that would result from discontinuation of MB as a fumigant for imports. In fiscal

[4] ''Costs and Benefits of Irradiation Versus Methyl Bromide Fumigation for Disinfestation of U.S. Fruit and Vegetable Imports,'' by Kenneth W. Forsythe, Jr. and Phylo Evangelou, ERS Staff Report No. AGES 9412, March 1994.

year 1996, 14 percent of imported fruits, nuts, and vegetables, valued at about $345 million, were treated with MB, 80 percent at U.S. ports and 20 percent in preclearance programs in foreign locations.[5] Although temperature-modifying treatments are possible alternatives for some fruits and vegetables, MB fumigation is the principal, and sometimes sole, phytosanitary treatment available for many commodities.

The 1994 study focused on short-and medium-term costs and benefits of irradiation treatment in off-season U.S. import markets for grapes, nectarines, okra, peaches, and plums. Grapes comprise over 80 percent, by value, of imported fruits and vegetables fumigated with MB, but they have a low tolerance for irradiation. When grapes were included in the analysis, irradiation treatment costs, in 1998 dollars, ranged from 1.6 to 3.9 cents per pound. Excluding grapes, irradiation cost estimates ranged from 3.4 to 3.9 cents per pound.[6] These unit costs reflect the substantial economies of size that could be captured by irradiation facilities, due to the concentration of imported fruit at certain ports of arrival.

Preshipment and quarantine uses of MB, along with critical agricultural and emergency uses, are exempted from the MB phaseout required by the Clean Air Act.[7] These exemptions essentially segment the MB market into restricted and unrestricted parts. Demand for MB used for exempted purposes is expected to remain unaffected as its use as a soil fumigant is restricted. However, reduced production due to the phaseout may cause the price of MB used for phytosanitary purposes to rise, due to an increase in the unit cost of production. Most MB in the world is manufactured by only three companies, two in the United States and one in Israel. Whether their economies of production can be maintained will depend on the demand for MB for exempted purposes in the United States and other developed countries, and overall demand in developing countries (where final phaseout is scheduled under the Montreal Protocol for 2015).

The demand for irradiation as a treatment alternative will be influenced by product quality and phytotoxicity issues. Product shelf life can be extended by irradiation. Moreover, some fruits and vegetables that are damaged by fumigation or temperature-modifying treatments are tolerant of irradiation. On the other hand, as indicated above for grapes, some fruits and vegetables are considered not very tolerant of irradiation. Assuming consumers accept irradiation as a phytosanitary treatment, its use will be determined not only by the availability of alternative treatments and relative costs but also by its enhancing or diminishing effects on product quality.

When the latter range of unit costs (3.4 to 3.9 cents per pound) are applied to fumigated quantities of 11 varieties of fruits imported in fiscal year 1996 that have a high or medium tolerance of irradiation, costs of irradiation treatment range, in 1998 dollars, between $2.7 million and $3.1 million.[8] Applying MB fumigation costs assumed in the 1994 study, 0.6 to 1.2 cents per pound in 1998 dollars, yields a total treatment cost of $0.5 million to $0.9 million for this same set of imports. It is apparent that the use of irradiation for phytosanitary purposes is probably not a cost-competitive alternative to MB fumigation at present. However, the phaseout of MB as a soil fumigant may result in an increase in its unit cost of production, thereby making the cost of irradiation and other treatment alternatives more competitive.

Adopting this rule would broaden the choices among phytosanitary treatment alternatives for U.S. fruit and vegetable importers. No net societal gains and losses other than small price-related changes are expected from this proposed rule if irradiation is used only to treat fruits and vegetables that would have been imported otherwise using an alternative treatment. Income earned by firms providing the irradiation services would be income forgone by the displaced fumigators or other treatment providers. But if irradiation enables importations that would not otherwise occur, then societal gains (increased imports) could be attributed to its phytosanitary use. Irradiation treatment most likely will both serve as an alternative treatment for a fraction of current imports and stimulate additional imports for certain fruits and vegetables, such as papaya, that need to be treated for fruit flies and have a high tolerance for irradiation.

Allowing irradiation to be used as a phytosanitary treatment for 11 fruit fly species and one seed weevil species would most immediately benefit four firms, three of which are small entities, that currently provide irradiation services on contract for sterilization and decontamination purposes. Participation of these firms, and entry of other firms, in the treatment of imported fruits and vegetables will depend upon the demand that develops for irradiation in relation to alternative treatments.

The major alternative to this proposed rule would be to not allow these irradiation treatments. In that case, importers and irradiation businesses would not accrue the benefits described above, and firms providing existing treatment alternatives would continue operating as at present (with MB fumigation becoming less competitive as its supply is constrained).

This proposed rule contains various recordkeeping and reporting requirements. These requirements are described in this document under the heading ''Paperwork Reduction Act.''

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have

[5] ''Quarantine Uses of Methyl Bromide by the United States, Fiscal Year 1996'' (Draft), APHIS-PPD-PAD, April 1997; available in the APHIS reading room (see **ADDRESSES**).

[6] To adjust irradiation unit costs estimated in the 1994 study from 1987 dollars to 1998 dollars, values are multiplied by a factor of 1.23 (producer price index for capital equipment, series ID: WPSSOP3200, Bureau of Labor Statistics, U.S. Dept. of Labor).

[7] Ten percent of methyl bromide used annually in agriculture in the United States is for commodity and quarantine treatment, compared to 85 percent for soil fumigation and 5 percent for structural fumigation. The 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act (Public Law 105–277) made specific changes to the Clean Air Act, to harmonize the U.S. phaseout of methyl bromide with the Montreal Protocol phaseout schedule for developed countries. This schedule requires U.S. methyl bromide production and importation reductions (from 1991 levels) of 25 percent in 1999, 50 percent in 2001, 70 percent in 2003, and 100 percent in 2005; exempted from this phaseout schedule are critical agricultural, emergency, and preshipment and quarantine uses. With respect to traded commodities, the amendment states that ''the [EPA] Administrator shall exempt the production, importation, and consumption of methyl bromide to fumigate commodities entering or leaving the United States or any State (or political subdivision thereof) for purposes of compliance with Animal and Plant Health Inspection Service requirements * * * '' (www.epa.gov/ozone/mbr/mbrqa.html).

[8] The 11 fruits are apricot, banana/plantain, grapefruit, orange, papaya, peach/nectarine, pineapple, plum, strawberry, tangerine, and tomato. The combined weight of import shipments of these fruits that were fumigated with MB in fiscal year 1996 was approximately 78.3 million pounds. This represented only 2.43 percent, by weight, of total imports of these 11 fruits (see, *op. cit.,* ''Quarantine Uses of Methyl Bromide by the United States, Fiscal Year 1996'' [Draft], Table 1). The range of costs is probably underestimated, since it assumes economies of size would be captured in all cases.

been prepared for this proposed rule. The assessment provides a basis for the conclusion that the irradiation methods proposed in this rule would not present a risk of introducing or disseminating plant pests and would not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection 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 copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 98–030–1. Please send a copy of your comments to: (1) Docket No. 98–030–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

We are proposing to authorize irradiation as a treatment for 11 species of fruit flies and one species of seed weevil in imported fruits and vegetables. This proposal would facilitate the importation of fruits and vegetables by giving importers another alternative to currently approved treatments required for articles attacked by these species of fruit flies and mango seed weevils.

Implementing this rule would necessitate the use of seven new paperwork collection activities (in the form of a compliance agreement, 24-hour notification, labeling requirements, dosimetry recordings, requests for dosimetry device approval, recordkeeping requirements, and requests for facility approval).

Labeling requirements represent a substantial part of the paperwork burden. The proposed rule would require that pallet loads of irradiated fruits and vegetables be marked by irradiation facility personnel or by the shipper with treatment lot numbers, packing and treatment facility identification and locations, and dates of packing and treatment. This information would allow an inspector to identify the treatment lots and trace them back to the packing and treatment facilities. The burden of this marking requirement would increase for importers who arrange to have pallet loads broken apart into individual cartons before entry into the United States, because, in such cases, individual cartons would have to bear the required information to allow successful traceback.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond, such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Estimate of burden: Public reporting burden for this collection of information is estimated to average .0825 hours per response.

Respondents: Irradiation facilities and shippers.

Estimated annual number of respondents: 125.

Estimated annual number of responses per respondent: 999.

Estimated annual number of responses: 124,885.

Estimated total annual burden on respondents: 10,305.

Copies of this information collection can be obtained from: Clearance Officer, OCIO, USDA, Room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

List of Subjects

7 CFR Part 305

Irradiation, Phytosanitary treatment, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements.

7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Logs, Nursery Stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend title 7, chapter III, of the Code of Federal Regulations as follows:

1. A new part 305 would be added to read as follows:

PART 305—PHYTOSANITARY TREATMENTS

Sec.

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, and 371.2(c).

§ 305.1 Definitions.

The following definitions apply for the purposes of this part:

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

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

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

Dosimeter. A device that, when irradiated, exhibits a quantifiable

change in some property of the device that can be related to absorbed dose in a given material using appropriate analytical instrumentation and techniques.

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

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

(a) Approved doses. Irradiation at the following doses for the specified fruit flies and seed weevils, carried out in accordance with the provisions of this section, is approved as a treatment for all fruits and vegetables:

IRRADIATION FOR FRUIT FLIES AND SEED WEEVILS IN IMPORTED FRUITS AND VEGETABLES

Scientific name	Common name	Dose (gray)
Bactrocera dorsalis	Oriental fruit fly	250
Ceratitis capital	Mediterranean fruit fly	225
Bactrocera cucurbitae	Melon fly	210
Anastrepha fraterculus	South American fruit fly	150
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
Bactrocera latifrons	Malaysian fruit fly	150
Cryptorhynchus mangiferae	Mango seed weevil	100

(b) *Location of facilities.* Where certified irradiation facilities are available, an approved irradiation treatment may be conducted for any fruit or vegetable either prior to shipment to the United States or in the United States. Irradiation facilities certified under this section may be located in any State on the mainland United States except Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, and Virginia. Prior to treatment, the fruits and vegetables to be irradiated may not move into or through any of the States listed in this paragraph, except that movement is allowed through Dallas/Fort Worth, Texas, as an authorized stop for air cargo, or as a transloading location for shipments that arrive by air but that are subsequently transloaded into trucks for overland movement from Dallas/Fort Worth into an authorized State by the shortest route.

(c) *Compliance agreement with importers and facility operators for irradiation in the United States.* If irradiation is conducted in the United States, both the importer and the operator of the irradiation facility must sign compliance agreements with the Administrator. In the facility compliance agreement, the facility operator must agree to comply with any additional requirements found necessary by the Administrator to prevent the escape, prior to irradiation, of any fruit flies that may be associated with the articles to be irradiated. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by the Administrator to ensure the shipment is not diverted to a destination other than treatment and to prevent escape of plant pests from the articles to be irradiated during their transit from the port of first arrival to the irradiation facility in the United States.

(d) *Compliance agreement with irradiation facilities outside the United States.* If irradiation is conducted outside the United States, the operator of the irradiation facility must sign a compliance agreement with the Administrator and the plant protection service of the country in which the facility is located. In this agreement, the facility operator must agree to comply with the requirements of this section, and the plant protection service of the country in which the facility is located must agree to monitor that compliance and to inform the Administrator of any noncompliance.

(e) *Certified facility.* The irradiation treatment facility must be certified by the Administrator. Recertification is required in the event of an increase or decrease in radioisotope, a major modification to equipment that affects the delivered dose, or a change in the owner or managing entity of the facility. Recertification also may be required in cases where a significant variance in dose delivery has been measured by the dosimetry system. In order to be certified, a facility must:

(1) Be capable of administering the minimum absorbed ionizing radiation doses specified in paragraph (a) of this section to the fruits and vegetables; [1]

(2) Be constructed so as to provide physically separate locations for treated and untreated fruits and vegetables, except that fruits and vegetables traveling by conveyor directly into the irradiation chamber may pass through an area that would otherwise be separated. The locations must be separated by a permanent physical barrier such as a wall or chain link fence 6 or more feet high to prevent transfer of cartons.

(3) If the facility is located in the United States, the facility will only be certified if the Administrator determines that regulated articles will be safely transported to the facility from the port of arrival without significant risk that plant pests will escape in transit or while the regulated articles are at the facility.

(f) *Treatment monitoring.* Treatment must be monitored by an inspector. This monitoring must include inspection of treatment records and unannounced inspections of the facility by an inspector. Facilities that carry out continual irradiation operations must notify an inspector at least 24 hours before the date operations commence.[2] Facilities that carry out periodic irradiation operations must notify an inspector of scheduled operations at least 24 hours before scheduled operations.

(g) *Packaging.* Fruits and vegetables that are irradiated in accordance with

[1] The maximum absorbed ionizing radiation dose and the irradiation of food is regulated by the Food and Drug Administration under 21 CFR part 179.

[2] Inspector means any employee of the Animal and Plant Health Inspection Service, or other person, authorized by the Administrator in accordance with law to enforce the provisions of the regulations of this part. Inspectors are assigned to local offices of the Animal and Plant Health Inspection Service, which are listed in telephone directories.

this section must be packaged in cartons in the following manner:

(1) All irradiated fruits and vegetables must be shipped in the same cartons in which they are irradiated. Irradiated fruits and vegetables may not be packaged for shipment in a carton with nonirradiated fruits and vegetables.

(2) For all fruits and vegetables irradiated prior to arrival in the United States:

(i) The fruits and vegetables to be irradiated must be packaged either:

(A) In insect-proof cartons that have no openings that will allow the entry of fruit flies. The cartons must be sealed with seals that will visually indicate if the cartons have been opened. The cartons may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the articles in the carton; [3] or

(B) In noninsect-proof cartons that are stored immediately after irradiation in a room completely enclosed by walls or screening that completely precludes access by fruit flies. If stored in noninsect-proof cartons in a room that precludes access by fruit flies, prior to leaving the room each pallet of cartons must be completely enclosed in polyethylene, shrink-wrap, or another solid or netting covering that completely precludes access to the cartons by fruit flies.

(ii) To preserve the identity of treated lots, each pallet-load of cartons containing the fruits and vegetables must be wrapped before leaving the irradiation facility in one of the following ways:

(A) With polyethylene shrink wrap;

(B) With net wrapping; or

(C) With strapping so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap.

(iii) Packaging must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment. Pallets that remain intact as one unit until entry into the United States may have one such label per pallet. Pallets that are broken apart into smaller units prior to or during entry into the United States must have the required label information on each individual carton.

(h) *Dosimetry systems at the irradiation facility.* (1) Dosimetry mapping must indicate the doses needed to ensure that all the commodity will receive the minimum dose prescribed.

(2) Absorbed dose must be measured using an accurate dosimetry system that ensures that the absorbed dose meets or exceeds the absorbed dose required by paragraph (a) of this section (150, 210, 225, or 250 Gray, depending on the target species of fruit fly).

(3) The utilization of the dosimetry system, including the number and placement of dosimeters used, must be in accordance with American Society for Testing and Materials (ASTM) standards.[4]

(i) *Records.* An irradiation processor must maintain records of each treated lot for 1 year following the treatment date and must make these records available for inspection by an inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except holidays). These records must include the lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

(j) *Request for certification and inspection of facility.* Persons requesting certification of an irradiation treatment facility must submit the request for approval in writing to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Oxford Plant Protection Center, 901 Hillsboro Street, Oxford, NC 27565. The initial request must identify the owner, location, and radiation source of the facility, and the applicant must supply additional information about the facility construction, treatment protocols, and operations upon request by APHIS if APHIS requires additional information to evaluate the request. Before the Administrator determines whether an irradiation facility is eligible for certification, an inspector will make a personal inspection of the facility to determine whether it complies with the standards of this section.

(k) *Denial and withdrawal of certification.* (1) The Administrator will withdraw the certification of any irradiation treatment facility upon written request from the irradiation processor.

(2) The Administrator will deny or withdraw certification of an irradiation treatment facility when any provision of this section is not met. Before withdrawing or denying certification, the Administrator will inform the irradiation processor in writing of the reasons for the proposed action and provide the irradiation processor with an opportunity to respond. The Administrator will give the irradiation processor an opportunity for a hearing regarding any dispute of a material fact, in accordance with rules of practice that will be adopted for the proceeding. However, the Administrator will suspend certification pending final determination in the proceeding if he or she determines that suspension is necessary to prevent the spread of any dangerous insect. The suspension will be effective upon oral or written notification, whichever is earlier, to the irradiation processor. In the event of oral notification, written confirmation will be given to the irradiation processor within 10 days of the oral notification. The suspension will continue in effect pending completion of the proceeding and any judicial review of the proceeding.

(l) *Department not responsible for damage.* This treatment is approved to assure quarantine security against the listed fruit flies. From the literature available, the fruits and vegetables authorized for treatment under this section are believed tolerant to the treatment; however, the facility operator and shipper are responsible for determination of tolerance. The Department of Agriculture and its inspectors assume no responsibility for any loss or damage resulting from any treatment prescribed or monitored. Additionally, the Nuclear Regulatory Commission is responsible for ensuring that irradiation facilities are constructed and operated in a safe manner. Further, the Food and Drug Administration is responsible for ensuring that irradiated foods are safe and wholesome for human consumption.

PART 319—FOREIGN QUARANTINE NOTICES

2. The authority citation for part 319 would continue to read as follows:

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, and 371.2(c).

3. In § 319.56–2, a new paragraph (k) would be added to read as follows:

§ 319.56–2 Restrictions on entry of fruits and vegetables.

* * * * *

(k) Any fruit or vegetable that is required by this subpart or the Plant Protection and Quarantine Treatment Manual to be treated or subjected to other growing or inspection requirements to control one or more of the 11 species of fruit flies and one

[3] If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Oxford Plant Protection Center, 901 Hillsboro Street, Oxford, NC 27565.

[4] Designation E 1261–94, ''Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing,'' American Society for Testing and Materials, *Annual Book of ASTM Standards.*

species of seed weevil listed in § 305.2(a) of this chapter as a condition of entry into the United States may instead be treated by irradiation in accordance with part 305 of this chapter.

4. In § 319.56–2x, paragraph (a), the introductory text preceding the table would be revised to read as follows:

§ 319.56–2x Administrative instructions; conditions governing the entry of certain fruits and vegetables for which treatment is required.

(a) The following fruits and vegetables may be imported into the United States only if they have been treated in accordance with the Plant Protection and Quarantine (PPQ) Treatment Manual, which is incorporated by reference at § 300.1 of this chapter. Treatment by irradiation in accordance with part 305 of this chapter may be substituted for treatments in the PPQ Treatment Manual for the mango seed weevil *Cryptorhynchus mangiferae* or for one or more of the following 11 species of fruit flies: *Anastrepha ludens, Anastrepha obliqua, Anastrepha serpentina, Anastrepha suspensa, Bactrocera cucurbitae, Bactrocera dorsalis, Bactrocera tryoni, Bactrocera jarvisi, Bactrocera latifrons, and Ceratitis capitata.*

* * * * *

Done in Washington, DC, this 23rd day of May 2000.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–13291 Filed 5–25–00; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1792

RIN 0572–AB47

Seismic Safety

AGENCY: Rural Utilities Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Utilities Service (RUS) proposes to amend its regulations to update and simplify the requirements of the agency. This revised rule would provide RUS borrowers, grant recipients, Rural Telephone Bank (RTB) borrowers and the public with updated rules for compliance with seismic safety requirements for new building construction using RUS or RTB loan, grant or guaranteed funds or funds provided through lien accommodations or subordinations approved by RUS or RTB. The proposed revision would identify model codes and standards found to provide a required level of seismic safety.

DATES: Written comments must be received by RUS on or before July 25, 2000.

ADDRESSES: Written comments should be addressed to George J. Bagnall, Director, Electric Staff Division, U.S. Department of Agriculture, Rural Utilities Service, Room 1246 South Building, Stop 1569, 14th & Independence Ave., SW., Washington, DC 20250–1569. Telephone 202–720–1900. RUS requests a signed original and three copies of all comments (7 CFR 1700.4). Comments will be available for public inspection during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Mr. Donald Heald, Structural Engineer, Transmission Branch, Electric Staff Division, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW, STOP 1569, Washington, DC 20250–1569. Telephone: (202) 720–9102. Fax: (202) 720–7491.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12372

This proposed rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with State and local offices. See the final rule related notice entitled ''Department Programs and Activities Excluded from Executive Order 12372'' (50 FR 47034).

Executive Order 12988

This proposed rule has been reviewed in accordance with Executive Order 12988, Civil Justice Reform. RUS has determined that this proposed rule meets the applicable standards provided in section 3 of the Executive Order. In addition, all State and local laws and regulations that are in conflict with this rule will be preempted; no retroactive effect will be given to this rule; and, in accordance with section 212(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6912(e)) administrative appeal procedures, if any are required, must be exhausted prior to initiating litigation against the Department or its agencies.

Regulatory Flexibility Act Certification

The Administrator of RUS has determined that this rule will not have significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The RUS and RTB loan programs provide borrowers with loans at interest rates and terms that are more favorable than those generally available from the private sector. Borrowers, as a result of obtaining federal financing, receive economic benefits that exceed any direct cost associated with RUS regulations and requirements.

Information Collection and Recordkeeping Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), RUS invites comments on this information collection for which RUS intends to request approval from the Office of Management and Budget (OMB).

Comments on this notice must be received by July 25, 2000.

Comments are invited on (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumption used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques on other forms of information technology.

Comments may be sent to F. Lamont Heppe, Jr., Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., Stop 1522, Room 4034 South Building, Washington, D.C. 20250–1522.

For further information contact Mr. Donald Heald, Structural Engineer, Transmission Branch, Electric Staff Division, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW, STOP 1569, Washington, DC 20250–1569. Telephone: (202) 720–9102. Fax: (202) 720–7491.

Title: Seismic Safety of New Building Construction.

OMB Control Number: 0572–0099.

Type of Request: Revision of a currently approved collection.

Abstract: The Earthquake Hazards Reduction Act of 1977 (42 U.S.C. 7701