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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 300 and 318

[Docket No. 95-069-2]

Papaya, Carambola, and Litchi From Hawaii

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are increasing the irradiation treatment dose required for papayas intended for interstate movement from Hawaii and allowing carambolas to be moved interstate from Hawaii with irradiation treatment. We are also allowing litchis to be moved interstate from Hawaii if they are inspected and found free of the litchi fruit moth and other plant pests and undergo irradiation or hot water treatment for fruit flies. We are allowing papayas, carambolas, and litchis from Hawaii to undergo irradiation treatment either in Hawaii or in non-fruit fly supporting areas of the mainland United States. In addition, we are making several amendments to the requirements for irradiation procedures and facilities and the handling of treated and untreated fruits and vegetables. Finally, we are amending the definition for *inspector* to include State plant regulatory officials designated by the Administrator of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture. These actions will facilitate the interstate movement of papayas, carambolas, and litchis from Hawaii while continuing to provide protection against the spread of injurious plant pests from Hawaii to other parts of the United States.

EFFECTIVE DATE: July 10, 1997. The incorporation by reference of certain publications listed in the regulations is

approved by the Director of the Federal Register as of July 10, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Peter M. Grosser, Senior Staff Officer, Port Operations, PPQ, APHIS, 4700 River Road Unit 139, Riverdale, MD 20737-1236, (301) 734-6799.

SUPPLEMENTARY INFORMATION:

Background

The Hawaiian Fruits and Vegetables regulations, contained in 7 CFR 318.13 through 318.13-17 (referred to below as the regulations), govern, among other things, the interstate movement of fruits and vegetables, including papayas, from Hawaii. Regulation is necessary to prevent the spread of the Mediterranean fruit fly (*Ceratitis capitata*), the melon fly (*Bactrocera cucurbitae*), and the Oriental fruit fly (*Bactrocera dorsalis*), which occur in Hawaii. These types of fruit flies are collectively referred to in this document as Trifly.

The regulations allow papayas to be moved interstate from Hawaii to any destination in the United States if, among other things, they have been treated for Trifly. One approved treatment for Trifly in papayas is irradiation. Prior to the effective date of this final rule, § 318.13-4f provided for irradiation of papayas, but no other fruits, at an approved facility in Hawaii at an irradiation dose of 150 Gray (15 krad).

On July 23, 1996, we published in the **Federal Register** (61 FR 38108-38114, Docket No. 95-069-1) a proposal to amend the regulations by increasing the irradiation treatment dose required for papayas intended for interstate movement from Hawaii; allowing carambolas to be moved interstate from Hawaii with irradiation treatment; allowing litchis to be moved interstate from Hawaii if they are inspected and found free of the litchi fruit moth and undergo irradiation or hot water treatment for fruit flies; allowing papayas, carambolas, and litchis from Hawaii to undergo irradiation treatment either in Hawaii or in non-fruit fly supporting areas of the mainland United States; making several amendments to the requirements for irradiation procedures and facilities and the handling of treated and untreated fruits and vegetables; and amending the definition of *inspector* to include State plant regulatory officials designated by the Administrator of the Animal and

Plant Health Inspection Service (APHIS), U.S. Department of Agriculture.

We solicited comments concerning our proposal for 30 days ending August 22, 1996. We received 45 comments by that date. They were from growers, producers, university personnel, and representatives of industry, irradiation associations, and State governments. One commenter supported the proposed rule in its entirety. The remaining 44 commenters had concerns about portions of the proposed rule. Their concerns are discussed below.

Comment: APHIS should not allow Trifly host fruit from Hawaii to be shipped to the mainland United States for treatment. Treatments should be conducted before the fruit leaves Hawaii. Arrival of untreated Trifly host material on the mainland United States, even in non-fruit fly supporting areas, would present too great a risk of Trifly being introduced into susceptible States. Factors contributing to this risk include misrouting, diversion of shipments, and repackaging and redistribution prior to treatment; the possibility of planes carrying untreated fruit crashing in susceptible States; and the possible establishment of Trifly in northern States during the summer months, with subsequent movement of infected host material into susceptible States.

Response: With the careful growing practices of Hawaii's commercial growers, such as administering pre-harvest chemical controls and keeping production fields clear of fallen fruit during harvest, we believe that occurrence of Trifly in cartons of untreated fruit from Hawaii will be rare. We believe that the packaging and movement provisions established by this rule for shipments of papaya, carambola, and litchi moving interstate to the mainland United States from Hawaii for treatment will further protect the mainland United States from the introduction of Trifly.

Specifically, untreated carambola, litchi, and papaya moving interstate to the mainland United States for treatment may not be moved with treated fruits or vegetables. This will prevent treated commodities from becoming infested with Trifly, and help ensure that untreated fruit is not inadvertently distributed in the United States with treated fruit. Although our rule allows untreated fruit bound for

treatment on the mainland United States to be packaged in either non-vented or vented cartons, any Trifly that might be present in the shipment would most likely be eggs and larvae, and it is unlikely that eggs and larvae would escape from normal vented packaging.

In addition, in the unlikely event that a shipment of untreated papaya, carambola, or litchi from Hawaii contains an injurious plant pest that escapes from a carton after arriving on the mainland United States, the areas into which shipments of untreated fruit from Hawaii may move are limited to those where Trifly would not be able to sustain a reproducing population. Irradiation treatment on the mainland United States may not be conducted in Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, or Virginia. Prior to treatment, the papaya, carambola, and litchi may not move into or through Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, or Virginia, except that Dallas/Fort Worth, Texas, is an authorized stop for air cargo and 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. In addition, both treated and untreated litchi from Hawaii may not be moved into or distributed in the State of Florida.

Apart from restricting the movement into Florida of litchi from Hawaii, we are establishing these movement restrictions because cooler climates will not support the establishment of successive generations of fruit flies. All three species of fruit fly identified in this document are distributed around the world but only establish reproducing populations in tropical, subtropical, and Mediterranean climates. For example, these species of fruit fly have had ample opportunity to establish reproducing populations in more northern countries such as Canada, Germany, and The Netherlands, where untreated host material has been imported from countries with climates suitable for fruit fly establishment for many years; however, the cold climates of these three northern countries have prevented the establishment of successive populations of fruit flies. We are confident that these three species of fruit fly do not have a life stage that can survive the cold winters of our northern tier States. Additionally, we have been

cold treating fruit fly host material from foreign countries in the northern United States for many years, and we have not recorded an established population of fruit flies in any northern State, during either the summer months or at any other time during the year, as a result of these imports. Therefore, we do not believe that the interstate movement of Hawaiian fruit for treatment on the mainland United States presents a risk of establishing Trifly in States into which Hawaiian fruit may move prior to treatment during the summer months or at other times during the year, and we, therefore, do not expect infested host material to move from northern States into more susceptible southern States prior to treatment for fruit flies.

Also, papaya, carambola, and litchi moved from Hawaii to the mainland United States for treatment must be treated prior to distribution on the mainland United States. The irradiation treatment for fruit flies, as well as the other treatments outlined in our proposal, meets probit 9 quarantine security. Probit 9 security means that no more than 32 per 1,000,000 treated individuals (such as fruit flies) will pass through treatment and still emerge as adults. Since it is extremely unlikely that a consignment of fruit from Hawaii could be infested at such a high rate, a probit 9 level treatment assures that essentially all target pests will be effectively treated so as to prevent their adult emergence. Probit 9 is a longstanding APHIS policy. We believe that probit 9 treatment procedures are sufficient to prevent the introduction and establishment of plant pests on the mainland United States.

We acknowledge that there is always the risk of misrouting, diversion of shipments, or a plane crash, but this risk is negligible. Further, in order to prevent the accidental misrouting or deliberate diversion of shipments of untreated fruit from Hawaii bound for treatment facilities on the mainland United States, each shipment of fruit from Hawaii requiring treatment on the mainland United States must move under limited permit. The limited permit will be issued by inspectors in Hawaii, who will notify APHIS personnel on the mainland United States of the issuance of the limited permit. The shipment of untreated fruit will then move interstate to a port staffed by APHIS personnel on the mainland United States. Therefore, at all points during the interstate movement, authorized personnel will be on hand to help prevent accidental misrouting, deliberate diversion, or repackaging and redistribution of untreated Hawaiian fruit.

Therefore, we are making no changes to the proposed rule in response to this comment.

Comment: In the absence of an irradiation facility in Hawaii, APHIS should require other treatments, such as cold or heat treatments, before fruit from Hawaii is moved interstate to the mainland United States.

Response: We feel that such cold or heat treatments of papaya, carambola, and litchi from Hawaii are not necessary because, combined with the packaging and movement requirements proposed for fruit from Hawaii, the proposed irradiation treatment for papaya, carambola, and litchi from Hawaii is sufficient to mitigate the risk of the introduction and establishment of Trifly and other injurious plant pests on the mainland United States. Additionally, for some time, we have permitted the untreated fruit fly host material of a number of foreign countries to undergo treatment on the mainland United States. We do not believe that there is cause to ask more of Hawaii than we do of those foreign countries. Therefore, we are making no changes to the proposed rule in response to this comment.

Comment: APHIS should require litchis from Hawaii to be cold treated prior to arrival on the mainland United States. Cold treatment is now required for litchis imported from foreign countries, such as Taiwan.

Response: We require cold treatment for litchis imported from Taiwan because of Oriental fruit fly (*Bactrocera dorsalis*) and litchi fruit borer (*Conopomorpha sinensis*). Though litchi from Hawaii also must be treated for Oriental fruit fly, as well as other pests, we do not believe that cold treatment is necessary for Hawaiian litchi. The hot water and irradiation treatments for litchi provided by this rule, combined with the movement restrictions discussed previously and the required inspection for litchi fruit moth and other plant pests, are sufficient to prevent the introduction of Trifly, litchi rust mite, and other injurious plant pests into the United States. In the future, we will consider any request to allow the cold treatment of Hawaiian litchi as an alternative to irradiation or hot water treatment. At this time, however, we are making no changes to the proposed rule in response to this comment.

Comment: APHIS should prohibit litchis from moving into either Florida or California unless the risk of introducing litchi rust mite, litchi fruit moth, Koa seedworm (also known as Macadamia nut borer), and light brown apple moth can be addressed. Regulations and stamps prohibiting the

movement of litchis into Florida will not keep infested fruit out of Florida.

Response: Because of Florida's commercial production of litchi, litchi from Hawaii will not be allowed to move into or be distributed in Florida, and cartons of litchi from Hawaii will be stamped with that information so that they are not inadvertently shipped to Florida.

Though we do not currently have sufficient data to judge the effect on litchi rust mite (*Eriophyes litchi*) of the irradiation dose adopted in this final rule for Trifly (250 Gray), we do expect, based on the available information, some deleterious effect on any litchi rust mites in a shipment of litchi that undergoes an irradiation treatment according to the provisions outlined in the proposal. Yet APHIS is not relying upon irradiation treatment as the primary means of reducing the risk associated with the litchi rust mite. We have determined that there is little chance that a litchi rust mite will stay on a litchi fruit throughout the growth, harvest, and packing of the litchi fruit. Litchi rust mite is most closely associated with the leaves and other plant parts of the litchi. Because we are only allowing the fruit of the litchi to be moved interstate from Hawaii, we believe that there is only a remote chance that litchi rust mite will be associated with fruit that is packed in a shipment of litchi moving interstate from Hawaii. We believe that the inspection, movement, and treatment provisions established for litchi by this rule will prevent litchi rust mite from being introduced into the mainland United States. However, as an added precaution to ensure protection of Florida's litchi industry, APHIS is prohibiting movement of Hawaiian litchi into Florida.

Further, we believe that litchi moved interstate from Hawaii under this rule will present a negligible risk of introducing litchi fruit moth (*Cryptophlebia ombrodelta*), Koa seedworm (*Cryptophlebia illepidia* [Butler]), or light brown apple moth (*Epiphyas postvittana*) anywhere on the mainland United States.

The cultural practices employed by Hawaiian tree fruit growers, such as administering pre-harvest chemical controls, keeping production fields clear of fallen fruit during harvest, and keeping field borders clear of hale koa (favored host of *Cryptophlebia* spp.), greatly reduce the possibility that litchi fruit moth, Koa seedworm, or light brown apple moth will be associated with Hawaiian litchi moving to the mainland United States. However, we are not depending on those growing

practices alone to mitigate the risk of the introduction of these pests on the mainland United States. Our rule also requires litchi from Hawaii to be inspected and found free of litchi fruit moth and other pests (including Koa seedworm and light brown apple moth) prior to treatment in Hawaii or prior to interstate movement if the litchi will be treated on the mainland United States. Each of these pests is readily detectable by inspection. We believe that the control and suppression measures used by Hawaiian commercial growers and the inspection of the litchi will mitigate the risk of the introduction of these pests onto the mainland United States.

In the preamble of our proposal, we stated that each shipment of litchi, whether treated in Hawaii or moving to the mainland United States for treatment, would be inspected in Hawaii prior to treatment or interstate movement for litchi fruit moth and other pests of concern. However, in the rule portion of our proposal, we did not make the inspection provisions clear for litchi undergoing irradiation treatment. Therefore, we have revised § 318.13-4f(b)(7)(i) and (ii) to clarify that all litchi from Hawaii must be inspected in Hawaii and found free of litchi fruit moth and other pests of concern prior to treatment or interstate movement.

Comment: APHIS should require untreated fruit, as well as treated fruit, to be packaged in a pest-proof carton, and the carton to be sealed before the fruit is to be moved from Hawaii. This would provide additional quarantine security.

Response: We proposed that all treated carambola, litchi, and papaya be packaged in pest-proof cartons to protect the fruit from re-infestation by Trifly. We proposed to allow untreated carambola, litchi, and papaya moving interstate to the mainland United States to move in either non-vented or in vented cartons. We proposed this flexibility for the packaging of untreated fruit because prevention of reinfestation is not an issue and because, as explained earlier in this document, any Trifly that might be present in the shipment would most likely be eggs and larvae, and it is unlikely that eggs and larvae could escape from normal vented packaging. Additionally, if Trifly eggs and larvae were present in the shipment, and if they reached maturity and escaped, it is unlikely that they could establish a reproducing population in the areas in which movement of untreated fruit will be authorized under the regulations because of either the relatively cool climate or the lack of suitable commercial host material in those areas.

Untreated carambola, litchi, and papaya must be treated before being distributed outside these areas.

We agree with the commenter that seals are a good way to help ensure the proper handling of shipments. Under our proposal, each carton of fruit treated in Hawaii that moves interstate to the mainland United States would be required to be sealed with seals that visually indicate if the cartons have been opened. However, we did not propose to require seals for cartons of untreated fruit. In response to this comment, we are requiring seals for shipping containers of untreated fruit moving interstate from Hawaii, as well as cartons of fruit treated in Hawaii. Because cartons of untreated Hawaiian fruit will be placed in sealed shipping containers prior to interstate movement to the mainland United States, we have determined that it is not necessary to seal each carton of untreated fruit. This provision would help ensure that no cartons within the sealed shipping container have been tampered with or removed. Therefore, we are amending § 301.13-4f(b)(4)(i) to require that shipping containers of untreated papaya, litchi, and carambola from Hawaii be sealed prior to interstate movement with seals that will visually indicate if the shipping containers have been opened.

Comment: The requirement that each carton of treated fruit be stamped "Treated—USDA, APHIS" should be retained to ensure product differentiation at the treatment facility and in the distribution channels afterward.

Response: In order to ensure that no cartons are added to or removed from a pallet load of cartons of Hawaiian fruit moving to the mainland United States, we proposed that pallet loads 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 proposed to require that pallet loads of treated carambola, litchi, and papaya be marked with treatment lot numbers, packing and treatment facility identification and locations, and dates of packing and treatment so that an inspector could identify the treatment lots of shipments and trace shipments back to the facilities where they were packed and treated. We proposed this method of labeling to replace the requirement that individual cartons be marked with a "Treated/USDA, APHIS" stamp. We believe that our proposed method will offer more information than our current method about a shipment or shipments

of fruit from Hawaii if an infestation is detected on the mainland United States. Therefore, we are making no changes to the proposed rule in response to this comment.

Comment: Only fruit treated in Hawaii should be required to be packaged in pest-proof cartons.

Response: We agree. Under our proposal, only carambola, litchi, and papaya from Hawaii that are treated in Hawaii will have to move in pest-proof cartons, in accordance with § 318.13-4f(b)(4)(i)(A). Carambola, litchi, and papaya from Hawaii that are treated on the mainland United States, and carambola, litchi, and papaya moving to the mainland United States for treatment, will not have to move in pest-proof cartons. Carambola, litchi, and papaya from Hawaii that are treated on the mainland United States will not be subject to further possible invasion by pests of concern after treatment, so we do not believe that cartons carrying these treated fruits need to be pest-proof. Fruit moving to the mainland United States for treatment also does not need to be shipped in pest-proof cartons for reasons explained earlier in this document. Therefore, we are making no changes to the proposed rule in response to this comment.

Comment: If fruit is allowed to move to the mainland United States from Hawaii for treatment, the production areas in Hawaii should be required to undergo malathion bait spray treatments, beginning 30 days before harvest begins and continuing until harvest ends.

Response: Treating production areas with bait spray, consisting of 95 percent malathion ULV mixed with a protein hydrolyzate applied at the rate of 2.4 ounces of malathion mixed with 9.6 ounces of protein hydrolyzate per acre, applied at 7 to 10 day intervals, with treatments commencing 30 days prior to harvest and continuing until harvest is complete, was a common practice in APHIS' eradication of the Mediterranean fruit fly (Medfly) in California in the 1980s. Bait spray treatments would be effective in suppressing the fruit fly population in production areas of Hawaii; however, it does not seem necessary to require bait spray treatments in addition to the treatment and other procedures required by this rule, because we believe these procedures provide security against the introduction and establishment of fruit flies and other pests on the mainland United States. Therefore, we are making no changes to the proposal in response to this comment.

Comment: It is important that an inspector be physically present at the

time of treatment either in Hawaii or on the mainland United States; therefore, the description of irradiation treatment procedures should include the phrase "under the supervision of an inspector."

Response: Regarding the phrase "under the supervision of an inspector" in relation to irradiation treatment, each and every irradiation treatment conducted on the mainland United States is not required to be directly supervised by an APHIS inspector. Instead, it is our intent to certify the irradiation facility and its operators initially and renew that certification every year. This certification, coupled with the placement of dosimeters, in accordance with ASTM standards, helps to ensure that the irradiation treatment process is completed carefully and accurately. Therefore, we are making no changes to the proposed rule in response to this comment.

Comment: If there are no dose indicators on a shipment, what will you do to be sure records will allow traceback?

Response: This rule requires a treatment facility to have dosimeters to accurately measure the absorbed irradiation dose for each lot of fruit treated at the facility. After the treatment is conducted, the shipment must be marked with its treatment lot number, packing and treatment facility identification and location, and date of packing and treatment so that an inspector can identify the treatment lot of the shipment and trace the shipment back to the facility where it was packed and treated. At the irradiation facility where the treatment took place, the records of irradiation treatment and the measurements of the dosimeters must be available for APHIS review and verification.

Comment: What is your rationale for increasing the irradiation dose from 150 Grays to 250 Grays?

Response: USDA scientists have done exhaustive reviews of the published research related to irradiation treatments for fruit flies. These scientists also have conducted research to prove the efficacy of quarantine treatments, including irradiation treatments. APHIS' adoption of 250 Gray as the minimum dose for the fruit flies of concern from Hawaii is based on the recommendation of these scientists after considering the level of quarantine security required by APHIS, the species of flies to be treated, and the level of confidence provided by current information.

Quarantine security involves defining two primary variables, the required endpoint and the level of efficacy. The endpoint for most quarantine treatments

is mortality. However, an advantage associated with irradiation is the opportunity to select from a range of endpoints including mortality, the inability to mature, and the inability for pests to reproduce (sterility). The endpoint adopted by APHIS for fruit flies is "preventing adult emergence." Mortality is deemed to be an excessive requirement that would result in significantly higher doses that are also more likely to cause damage to the commodity. Sterility as an endpoint provides quarantine security and is likely to require a lower dose, but it causes regulatory problems because the milder dose allows live flies to emerge from fruit. If detected, these flies could trigger regulatory actions because there is not currently a practical means to distinguish sterile flies from fertile flies. Therefore, the appropriate endpoint has been determined by APHIS to be "preventing adult emergence."

The level of efficacy required by APHIS is probit 9. As discussed above, a probit 9 level treatment assures that essentially all target pests will be effectively sterilized or destroyed.

The target pests for the treatment of Hawaiian fruit are the Trifly group, including the Oriental fruit fly, the Medfly, and the melon fly. The dose of 250 Gray has been determined by APHIS to be necessary to achieve quarantine security for the Oriental fruit fly. A dose of 225 Gray has been adopted by APHIS for Medfly, and a dose of 210 Gray has been adopted by APHIS for the treatment of melon fly (see a notice published in the **Federal Register** on Wednesday, May 15, 1996, 61 FR 24433-24439, Docket No. 95-088-1). Since any of the three species may be present in fruit for treatment from Hawaii, APHIS is requiring the dose for the most resistant species, the Oriental fruit fly.

A dose of 150 Gray has been widely recommended as a generic dose for all fruit flies. After consultation with USDA and other scientists, and careful review of the research, APHIS has determined that 150 Gray is an appropriate dose for several other species of fruit flies, including four species of *Anastrepha* and three other species of *Bactrocera*. However, we do not believe that the available information is adequate to support the adoption of 150 Gray as a generic dose for all fruit flies, given the level of quarantine security required by APHIS.

APHIS is hopeful that additional research and better information can be provided to support the adoption of lower doses, possibly below 150 Gray. Information of this nature will be considered by APHIS as it becomes

available, and treatment requirements will be adjusted to reflect the lowest possible effective dose that is deemed to be both operationally practical and scientifically supportable for the level of quarantine security required by APHIS for the pests of concern, including fruit flies. However, at this time, we have determined that, based on research, quarantine security requires an irradiation dosage of 250 Gray as an appropriate dose to achieve probit 9 efficacy. Therefore, we are making no changes to the proposed rule in response to this comment.

Comment: The increased irradiation dose of 250 Gray will not kill all fruit fly larvae in shipments of fruit from Hawaii and is not in line with the Notice of Policy, The Application of Irradiation to Phytosanitary Problems, as published in the **Federal Register** on May 15, 1996 (61 FR 24433-24439, Docket No. 95-088-1).

Response: We agree that a dose of 250 Gray will not kill all Trifly larvae in the shipments, but research and test treatments under commercial conditions demonstrate that a high percentage of larvae will in fact be killed when treated with a 250 Gray minimum dose. This is because, under commercial conditions, most of the treated lot will receive a dose two to three times the minimum in order to ensure that the low point in the load receives the minimum dose. However, the endpoint for quarantine security that has been adopted by APHIS is not larval mortality, but the inability of adults to emerge from fruit. We are confident that the research adequately supports 250 Gray as an appropriate dose to achieve probit 9 efficacy.

Regarding a possible contradiction of one or more of the policy statements contained in the Notice of Policy, The Application of Irradiation to Phytosanitary Problems, the policy notice referred to by the commenter states the intent of the Agency is to avoid regulatory overlap, conflict, and ambiguity through cooperation and by harmonizing requirements across agency, domestic, and international lines of authority. This is in recognition of the range of authorities involved with irradiation and the complexity of requirements placed on the irradiation industry. APHIS remains committed to this policy in the subject rule and as a standard for regulatory initiatives in general. For example, the role of the Food and Drug Administration and Nuclear Regulatory Commission is acknowledged and well-integrated into the authorization for the irradiation of Hawaiian fruits and vegetables (see § 318.13-4f(e)).

The issue of quarantine security, however, is clearly central to the charge and authority of APHIS. It is in this regard that the decision concerning dose becomes a function of APHIS' positions on the desired level of protection and the degree of confidence placed on information used to support various proposals. The primary principles to consider in this respect are consistency, equivalency, and the risk basis for requirements. However, the doses adopted by APHIS in some instances may vary from those adopted by other countries or the recommendations of international organizations when APHIS determines that there is a high risk which justifies and supports an increased level of protection. APHIS' doses are believed to be consistent with the level of quarantine security and the quality of supporting data used for similar treatment situations. APHIS remains open to any new information that may lead to lower dose levels and greater harmonization. However, at this time, we are making no changes to the proposed rule in response to this comment.

Comment: Technical corrections need to be made regarding the irradiation terminology (ASTM) in the proposal.

Response: We agree that technical corrections, including the replacement of the term "dose indicator" with the term "dosimeter" in § 318.13-4f(b)(6)(ii) and the amendment of footnote 6 of the rule portion of this document, need to be made in our irradiation terminology. Accordingly, we are amending § 318.13-4f(b)(6)(ii) to read "dosimeter" instead of "dose indicator," and footnote 6 to read "Designation E 1261, 'Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing,' American Society for Testing and Materials, Annual Book of ASTM Standards."

Comment: Only fruit (no leaves or stems) from Hawaii should be allowed to enter the mainland United States because fruit flies and other plant pests may hide in leaves and stems.

Response: We are only allowing the fruit of carambola, litchi, and papaya from Hawaii to move interstate to the mainland United States. It is customary in shipping such fruits that only the fruit, without leaves, stems, or other plant parts, be packaged in a shipment. Therefore, we are making no changes to the proposed rule in response to this comment.

Comment: Will you allow non-fruit fly host material, such as pineapples, in the same shipment as treated fruit?

Response: Untreated fruit, whether fruit fly host material or not, must not be packed in the same carton as treated

fruit (see § 318.13-4f(b)(2)(ii)). Non-fruit fly host material may be moved in the same pallet load as treated fruit because there is negligible risk that non-fruit fly host material would contain fruit flies that could re-infest treated fruit and because treated fruit must move to the mainland United States in pest-proof cartons.

Comment: The criteria for the locations of future mainland irradiation treatment facilities should be in line with the criteria for locations of cold treatment facilities to prevent the introduction and establishment of fruit flies on the mainland United States.

Response: We believe that fruit fly host material moving to the mainland United States from Hawaii for irradiation treatment should be allowed to be treated only at those locations that will not support the establishment of successive generations of fruit flies. At this time, we are limiting the areas where irradiation treatment may be conducted on the mainland United States to States other than Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, or Virginia. However, we are considering the possibility of allowing irradiation facilities to operate in other locations on the mainland United States where cold treatment of fruit flies has been approved.

Comment: Changing the definition of "inspector" will reduce the standard of inspection.

Response: Our proposed revision to the definition of "inspector" will allow State cooperators to inspect and issue limited permits for fruit moving interstate from Hawaii under our regulations. To be eligible for designation as an inspector under the regulations, a State plant regulatory official must have a bachelor's degree in the biological sciences, a minimum of 2 years' experience in State plant regulatory activities, and a minimum of 2 years' experience in recognizing and identifying plant pests known to occur within Hawaii. Six years' experience in State plant regulatory activities may be substituted for the degree requirement. As explained in our proposed rule, these requirements are based on the qualifications in 7 CFR 353 for State plant regulatory officials who provide phytosanitary certification for plants and plant products exported from the United States. We believe our expanded definition of "inspector" will facilitate the inspection process while continuing to provide protection against the spread of injurious plant pests from Hawaii to other parts of the United States.

Therefore, we are making no changes to the proposed rule in response to this comment.

We are also making nonsubstantive editorial changes for clarity.

We feel confident that with the provisions outlined in our proposal and in this document, carambola, litchi, and papaya can move interstate from Hawaii to the mainland United States without presenting a significant risk of pest introduction or establishment on the mainland United States.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule with the changes discussed above.

Effective Date

Though this rule does change certain irradiation dosage and packaging requirements for papaya treated in Hawaii, there are currently no irradiation facilities in Hawaii to treat papaya; therefore, no one will be adversely affected by this rule. The other provisions contained in this rule relieve restrictions on the interstate movement of papaya, carambola, and litchi from Hawaii to the mainland United States. As such, this is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. Immediate implementation of this rule is necessary to provide relief to those persons who are adversely affected by restrictions we no longer find warranted. The shipping season for litchi from Hawaii began in May and continues through August. Making this rule effective immediately will allow interested producers and others in the marketing chain to benefit during this year's shipping season. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The 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.

In accordance with 5 U.S.C. 604, we have performed a Final Regulatory Flexibility Analysis, which is set out below, regarding the impact of this final rule on small entities.

In accordance with 7 U.S.C. 162, the Secretary of Agriculture is authorized to promulgate regulations governing the

interstate movement of plants and plant products from a State or territory of the United States to prevent the spread of a dangerous plant disease or insect infestation new to or not widely prevalent or distributed within or throughout the United States.

This rule amends the regulations by increasing the irradiation treatment dose required for papayas intended for interstate movement from Hawaii, by allowing carambolas to be moved interstate from Hawaii with irradiation treatment, and by allowing litchis to be moved interstate from Hawaii if they are inspected and found free of the litchi fruit moth and other plant pests and undergo irradiation or hot water treatment for fruit flies. We are allowing papayas, carambolas, and litchis from Hawaii to undergo irradiation treatment either in Hawaii or in non-fruit fly supporting areas of the mainland United States. In addition, we are making several amendments to the requirements for irradiation procedures and facilities and the handling of treated and untreated fruits and vegetables. Finally, this rule amends the definition for *inspector* to include State plant regulatory officials designated by the Administrator of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture. These actions will facilitate the interstate movement of papayas, carambolas, and litchis from Hawaii while continuing to provide protection against the spread of injurious plant pests from Hawaii to other parts of the United States. Economic impacts associated with this rulemaking will largely be the result of untreated papayas, carambolas, or litchis being allowed to move to the mainland United States for irradiation treatment.

In our proposal, we solicited comments on the potential effects of the proposed action on small entities. In particular, we sought data and other information to determine the number and kind of small entities that may incur benefits or costs from the implementation of the proposed rule. We received one comment on the Initial Regulatory Flexibility Analysis contained in the proposed rule. The commenter said that our determination that the proposal was not economically significant was incorrect; the commenter remarked that the provisions of the proposal are economically significant, particularly if, after the adoption of the proposal, a pest eradication program must commence.

We believe that the treatment and other procedures established in this rule for the interstate movement of carambola, litchi, and papaya will

mitigate the risk of pest introduction and establishment on the mainland United States. Therefore, we do not believe that a pest eradication program will be necessary as a result of this rule, or that the rule will otherwise have a significant economic impact on U.S. entities, large or small. As discussed below, Hawaii produces a small quantity of carambola and litchi when compared to the production of these commodities in the rest of the United States, and Hawaiian papaya shipments to the mainland United States totaled less than half of the quantity of papaya that the United States imported from foreign nations in 1994.

Papayas

Papayas are produced commercially on about 340 farms in Hawaii. Nearly 65 percent of those farms are owned by individuals whose major occupation is not farming, while the balance are operated by individuals whose major occupation is farming.

Papaya farms with average annual revenues of less than \$500,000 are considered small. All papaya farms in Hawaii are therefore considered small.

In 1994, Hawaii produced 62 million pounds of papaya (valued at \$15 million). Fresh papaya comprised 56.2 million pounds of this total. During that year, Hawaii shipped about 37.8 million pounds of papaya. Shipment of fresh papaya to the mainland totaled about 19.4 million pounds, and the remainder was exported to other countries. Of the approximately 19.4 million pounds of fresh papayas shipped from Hawaii to the mainland in 1994, most went to the West Coast. Seventy-five percent of them were sold directly to retailers, and the rest were sold to wholesalers.

The United States imported about 41.2 million pounds of fresh papaya (valued at \$10.9 million) in 1994. Most of the imported papayas came from Mexico (80 percent), Belize (9.6 percent), Jamaica (6.3 percent), and the Dominican Republic (1.9 percent). The United States exported 18.4 million pounds of fresh papayas (valued at \$15.4 million) in 1994. The major importers were Japan (66.8 percent) and Canada (27.1 percent). Almost all United States exports of papayas go out of Hawaii, while all imports come into the mainland United States.

There are five firms currently operating nine papaya treatment facilities in the State of Hawaii. Four firms use the vapor-heat treatment method and one uses the dry heat (or high-temperature forced air) method. The total capacity of these treatment chambers is 85,000 pounds per run.

Both heat treatment methods have the potential to damage the papayas. They require the center of each papaya fruit to reach about 47 °C (about 117 °F), a temperature sufficient to kill fruit fly eggs and larvae. Because of variation in fruit size and ripeness, the papayas may not be uniformly heated. This may result in the fruit becoming lumpy and losing flavor. For both methods, careful control of the uniformity of fruit size and ripeness is necessary for effective treatment. In addition, both methods require between 4 and 6 hours of treatment. Efforts to speed up the process result in fruit which is either scalded externally or hardened on the inside. The cost of treatment for both methods ranges from 9 to 23 cents per pound.

Although the regulations currently allow papayas to be treated by irradiation in Hawaii, there are no irradiation facilities in that State. Allowing irradiation to be performed on the mainland appears to be an attractive option. The subsequent diversion of untreated papayas from Hawaii to the mainland would likely result in loss of business to the existing vapor heat and dry heat facilities. This could result in lay-offs and possibly the shut-down of some of these facilities. However, if papaya producers respond by producing more papayas, continuing traditional treatment for some and shipping others for irradiation, this will not necessarily occur.

Carambolas

The United States produced about 6 million pounds of carambola in 1994, with a total value of approximately \$4 million to \$4.5 million. In the United States, carambola is grown on about 100 farms. All of these farms have a market value of less than \$500,000 and are thus considered to be small businesses according to the Small Business Administration's size standards.

In 1994, Hawaii produced only about 50,700 pounds of carambola, valued at approximately \$38,000, on 30 farms. The provisions proposed in this rule concerning irradiation treatment of carambola fruits by the mainland facilities are expected to stimulate growth of the carambola industry in Hawaii and provide greater access to the larger mainland market.

No economic impact on mainland carambola growers is anticipated, since the total Hawaii production of carambola is less than one percent of the mainland production. Therefore, even in the unlikely event that Hawaii could ship 100 percent of its production to the mainland, supply would only increase by less than one percent. However,

mainland consumers would likely benefit from increased seasonal and regional availability, as well as from the increased variety of fresh carambola. Additionally, carambola growers in Hawaii would benefit from the opportunity to sell their product in a larger and more diverse market.

This rule will enable carambola from Hawaii to be irradiated at an existing irradiation facility on the mainland and is not expected to impose additional costs on carambola producers in Hawaii. We expect that carambola producers in Hawaii will benefit from the proposed irradiation treatment because this treatment can deliver better product quality, extended shelf life of the fruit, and cost effective treatment of the fruit. However, the overall impact of the carambola provisions of the proposed rule is expected to be insignificant.

Litchis

Litchis are produced commercially on 55 farms in Hawaii. In 1993, the United States produced about 770,000 pounds of litchi. Of that total, approximately 85,000 pounds was produced in Hawaii.

Litchi farms with average annual revenues of less than \$500,000 are considered small. All litchi farms in Hawaii are considered small.

The litchi industry in Hawaii has been constrained by the lack of an approved treatment for fruit flies since the cancellation of ethylene dibromide in 1984. Approving irradiation treatment of litchis on the mainland is expected to stimulate growth of the industry and provide access to the larger mainland market. No information is available on the effect of approving inspection and hot water treatment as an alternative method for moving litchis interstate.

The United States is a net importer of fresh litchi, with a total import of about 165,000 pounds in 1994. In 1994, nearly 70 percent of imported litchi came from Mexico; the remainder came from Israel. The total supply of litchi on the mainland is about 850,000 pounds. Wholesale prices of litchi range between \$1.00 per pound and \$4.50 per pound.

The economic impact on mainland litchi growers and prices on the mainland will not be significant. Even in the unlikely event that Hawaii shipped 25 percent of its production to the mainland, supply will increase by only about 2.3 percent. However, mainland consumers will benefit from increased seasonal and regional availability, an increased variety of fresh litchi, and stable prices. Additionally, litchi growers in Hawaii will benefit from the increased opportunity to sell

their product in a larger and more diverse market.

According to recent research conducted by the ARS, irradiation appears to be an effective treatment option that does not require control of either fruit size or ripeness. Irradiation typically requires only 40 minutes for treatment. The irradiation method may be more cost effective depending on volume treated, because it costs only about 5 to 12 cents per pound.

This rule is expected to benefit producers, since irradiation appears to offer a number of advantages over current treatment options, including greater flexibility of fruit size and ripeness, reduction in treatment time, improved effectiveness against pest infestation, better product quality, extended shelf life, and improved cost effectiveness. Consumers also may benefit from a better quality product. The overall impact upon supply, price, and competitiveness is expected to be insignificant.

This rule contains information collection requirements. These were described in detail in the proposed rule as required by the Paperwork Reduction Act of 1995. Further, as required by that Act, we solicited public comment on the proposed information collection requirements and submitted them to the Office of Management and Budget for approval. See the statement in this document under the heading "Paperwork Reduction Act."

The alternative to this rule is to take no action. We do not consider taking no action a reasonable alternative. Papayas may move interstate to the mainland United States only with thermal treatment, and carambolas and litchis are not currently moved interstate from Hawaii because of a lack of suitable treatment options. This rule will facilitate the interstate movement of papayas, carambolas, and litchis from Hawaii while continuing to provide protection against the spread of injurious plant pests from Hawaii to other parts of the United States.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. State and local laws and regulations that are inconsistent with this rule will be preempted. No

retroactive effect will be given to this rule. Administrative proceedings will not be required before parties may file suit in court challenging this rule.

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 final rule have been approved by the Office of Management and Budget (OMB). The assigned OMB control number is 0579-0123.

List of Subjects

7 CFR Part 300

Incorporation by reference, Plant diseases and pests, Quarantine.

7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Incorporation by reference, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

Accordingly, 7 CFR parts 300 and 318 are amended as follows:

PART 300—INCORPORATION BY REFERENCE

1. The authority citation continues to read as follows:

Authority: 7 U.S.C. 150ee, 154, 161, 162, and 167; 7 CFR 2.22, 2.80, and 371.2(c).

2. In § 300.1, paragraph (a), the introductory text is revised to read as follows:

§ 300.1 Materials incorporated by reference; availability.

(a) *Plant Protection and Quarantine Treatment Manual.* The Plant Protection and Quarantine Treatment Manual, which was reprinted on November 30, 1992, and includes all revisions through April 1997, has been approved for incorporation by reference in 7 CFR chapter III by the Director of the Office of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

* * * * *

PART 318—HAWAIIAN AND TERRITORIAL QUARANTINE NOTICES

3. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff, 161, 162, 164a, and 167; 7 CFR 2.22, 2.80, and 371.2(c).

4. In § 318.13-1, the definition for *Inspector* is amended to read as follows:

§ 318.13-1 Definitions.

* * * * *

Inspector. An employee of Plant Protection and Quarantine, or a State plant regulatory official designated by the Administrator to inspect and certify to shippers and other interested parties, as to the condition of the products inspected. To be eligible for designation, a State plant regulatory official must have a bachelor's degree in the biological sciences, a minimum of 2 years' experience in State plant regulatory activities, and a minimum of 2 years' experience in recognizing and identifying plant pests known to occur within Hawaii. Six years' experience in State plant regulatory activities may be substituted for the degree requirement.

* * * * *

5. In § 318.13-3, a new paragraph (b)(3) is added to read as follows:

§ 318.13-3 Conditions of movement.

* * * * *

(b) * * *

(3) Untreated fruits and vegetables from Hawaii may be moved interstate for irradiation treatment on the mainland United States if the provisions of § 318.13-4f are met and if the fruits and vegetables are accompanied by a limited permit issued by an inspector in accordance with § 318.13-4(c). The limited permit will be issued only if the inspector examines the shipment and determines that the shipment has been prepared in compliance with the provisions of this subpart.

* * * * *

6. A new § 318.13-4e is added to read as follows:

§ 318.13-4e Administrative instructions governing the movement of litchis from Hawaii to other States.

(a) Litchis may be moved interstate from Hawaii only in accordance with this section or § 318.13-4f and all other applicable provisions of this part.

(b) To be eligible for interstate movement under this section, litchi must be inspected and found free of the litchi fruit moth (*Cryptophlebia* spp.) and other plant pests by an inspector and then treated for fruit flies under the supervision of an inspector with a treatment listed in the Plant Protection and Quarantine Treatment Manual, which is incorporated by reference at § 300.1 of this chapter.

(c) Litchi from Hawaii may not be moved interstate into Florida. All cartons in which litchi from Hawaii are packed must be stamped "Not for importation into or distribution in FL."

7. Section 318.13-4f is revised to read as follows:

§ 318.13-4f Administrative instructions prescribing methods for irradiation treatment of certain fruits and vegetables from Hawaii.

(a) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of this section, is approved as a treatment for the following fruits and vegetables: carambola, litchi, and papaya.

(b) *Conditions of movement.* Fruits and vegetables from Hawaii may be authorized for movement in accordance with this section only if the following conditions are met:

(1) *Location.* The irradiation treatment must be carried out at an approved facility in Hawaii or on the mainland United States. Fruits and vegetables authorized under this section for treatment on the mainland may be treated 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, or Virginia. Prior to treatment, the fruits and vegetables may not move into or through Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, or Virginia, 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.

(2) *Approved facility.* The irradiation treatment facility and treatment protocol must be approved by the Animal and Plant Health Inspection Service. In order to be approved, a facility must:

(i) Be capable of administering a minimum absorbed ionizing radiation dose of 250 Gray (25 krad) to the fruits and vegetables;²

(ii) 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 six or more feet high to prevent transfer of cartons. Untreated fruits and vegetables shipped to the mainland United States from Hawaii in

²The maximum absorbed ionizing radiation dose and the irradiation of food is regulated by the Food and Drug Administration under 21 CFR part 179.

accordance with this section may not be packaged for shipment in a carton with treated fruits and vegetables;

(iii) Complete a compliance agreement with the Animal and Plant Health Inspection Service as provided in § 318.13-4(d) of this subpart; and

(iv) Be certified by Plant Protection and Quarantine for initial use and annually for subsequent use. Recertification is required in the event that an increase or decrease in radioisotope or a major modification to equipment that affects the delivered dose. Recertification may be required in cases where a significant variance in dose delivery is indicated.

(3) *Treatment monitoring.* Treatment must be carried out under the monitoring of an inspector. This monitoring must include inspection of treatment records and unannounced inspectional visits to the facility by an inspector. Facilities that carry out continual irradiation operations must notify an inspector at least 24 hours before the date of operations. Facilities that carry out periodic irradiation operations must notify an inspector of scheduled operations at least 24 hours before scheduled operations.³

(4) *Packaging.* (i) Fruits and vegetables that are treated in Hawaii must be packaged in the following manner:

(A) The cartons must have no openings that will allow the entry of fruit flies and must be sealed with seals that will visually indicate if the cartons have been opened. They may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the fruit in the carton.⁴

(B) The pallet-load of cartons must be wrapped before it leaves the irradiation facility in one of the following ways:

(1) With polyethylene sheet wrap;

(2) With net wrapping; or

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

(C) Packaging must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment.

(ii) Cartons of untreated fruits and vegetables that are moving to the

mainland United States for treatment must be shipped in shipping containers sealed prior to interstate movement with seals that will visually indicate if the shipping containers have been opened.

(iii) Litchi from Hawaii may not be moved interstate into Florida. All cartons in which litchi from Hawaii are packed must be stamped "Not for importation into or distribution in FL."

(5) *Dosage.* The fruits and vegetables must receive a minimum absorbed ionizing radiation dose of 250 Gray (25 krad).⁵

(6) *Dosimetry systems.* (i) Dosimetry must demonstrate that the absorbed dose, including areas of minimum and maximum dose, is mapped, controlled, and recorded.

(ii) Absorbed dose must be measured using a dosimeter that can accurately measure an absorbed dose of 250 Gray (25 krad).

(iii) The number and placement of dosimeters used must be in accordance with American Society for Testing and Materials (ASTM) standards.⁶

(7)(i) *Certification on basis of treatment.* A certificate shall be issued by an inspector for the movement of fruits and vegetables from Hawaii that have been treated and handled in Hawaii in accordance with this section. To be certified for interstate movement under this section, litchi from Hawaii must be inspected in Hawaii and found free of the litchi fruit moth (*Cryptophlebia* spp.) and other plant pests by an inspector before undergoing irradiation treatment in Hawaii for fruit flies.

(ii) *Limited permit.* A limited permit shall be issued by an inspector for the interstate movement of untreated fruits and vegetables from Hawaii for treatment on the mainland United States in accordance with this section. To be eligible for a limited permit under this section, untreated litchi from Hawaii must be inspected in Hawaii and found free of the litchi fruit moth (*Cryptophlebia* spp.) and other plant pests by an inspector.

(8) *Records.* Records or invoices for each treated lot must be made available for inspection by an inspector during normal business hours (8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays). An irradiation processor must maintain records as specified in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, and must make these

records available for inspection by an inspector. 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.

(c) *Request for approval and inspection of facility.* Persons requesting approval of an irradiation treatment facility and treatment protocol 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 St., Oxford, NC 27565. Before the Administrator determines whether an irradiation facility is eligible for approval, an inspector will make a personal inspection of the facility to determine whether it complies with the standards of paragraph (b)(2) of this section.

(d) *Denial and withdrawal of approval.* (1) The Administrator will withdraw the approval of any irradiation treatment facility when the irradiation processor requests in writing the withdrawal of approval.

(2) The Administrator will deny or withdraw approval of an irradiation treatment facility when any provision of this section is not met. Before withdrawing or denying approval, 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 approval pending final determination in the proceeding, if he or she determines that suspension is necessary to prevent the spread of any dangerous insect infestation. 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.

(e) *Department not responsible for damage.* This treatment is approved to assure quarantine security against the Trifly complex. From the literature available, the fruits and vegetables authorized for treatment under this section are believed tolerant to the treatment; however, the facility operator

³ Inspectors are assigned to local offices of the Animal and Plant Health Inspection Service, which are listed in telephone directories.

⁴ 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, Phytosanitary Issues Management Team, 4700 River Road Unit 140, Riverdale, Maryland 20737-1236.

⁵ See footnote 2.

⁶ Designation E 1261, "Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing," American Society for Testing and Materials, *Annual Book of ASTM Standards*.

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 supervised. 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.

Done in Washington, DC, this 30th day of June 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97-17672 Filed 7-9-97; 8:45 am]

BILLING CODE 3410-34-U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 97-056-3]

Mediterranean Fruit Fly; Additions to the Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the Mediterranean fruit fly regulations by expanding the current quarantined area in Hillsborough County, FL, and adding areas in Manatee and Polk Counties, FL, to the list of quarantined areas. The regulations restrict the interstate movement of regulated articles from the quarantined areas. This action is necessary on an emergency basis to prevent the spread of the Mediterranean fruit fly into noninfested areas of the continental United States.

DATES: Interim rule effective July 3, 1997. Consideration will be given only to comments received on or before September 8, 1997.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 97-056-3, 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. 97-056-3. 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. Michael B. Stefan, Operations Officer, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737-1236, (301) 734-8247; or e-mail: mstefan@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Mediterranean fruit fly, *Ceratitis capitata* (Wiedemann), is one of the world's most destructive pests of numerous fruits and vegetables. The Mediterranean fruit fly (Medfly) can cause serious economic losses. Heavy infestations can cause complete loss of crops, and losses of 25 to 50 percent are not uncommon. The short life cycle of this pest permits the rapid development of serious outbreaks.

The Mediterranean fruit fly regulations (7 CFR 301.78 through 301.78-10; referred to below as the regulations) restrict the interstate movement of regulated articles from quarantined areas to prevent the spread of Medfly to noninfested areas of the United States.

An interim rule effective on June 16, 1997, and published in the **Federal Register** on June 20, 1997 (62 FR 33537-33539, Docket No. 97-056-2), added a portion of Hillsborough County, FL, to the list of quarantined areas and restricted the interstate movement of regulated articles from the quarantined area.

Recent trapping surveys by inspectors of Florida State and county agencies and by inspectors of the Animal and Plant Health Inspection Service (APHIS) have revealed that an infestation of Medfly has occurred in an additional area in Hillsborough County and in portions of Manatee and Polk Counties, FL.

The regulations in § 301.78-3 provide that the Administrator of APHIS will list as a quarantined area each State, or each portion of a State, in which the Medfly has been found by an inspector, in which the Administrator has reason to believe that the Medfly is present, or that the Administrator considers necessary to regulate because of its inseparability for quarantine enforcement purposes from localities in which the Medfly has been found.

Less than an entire State will be designated as a quarantined area only if the Administrator determines that the State has adopted and is enforcing restrictions on the intrastate movement of the regulated articles that are

equivalent to those imposed on the interstate movement of regulated articles, and the designation of less than the entire State as a quarantined area will prevent the interstate spread of the Medfly. The boundary lines for a portion of a State being designated as quarantined are set up approximately four-and-one-half-miles from the detection sights. The boundary lines may vary due to factors such as the location of hosts, the location of transportation centers, such as bus stations and airports, the pattern of persons moving in that State, the number and patterns of distribution of the Medfly, and the use of clearly identifiable lines for the boundaries.

In accordance with these criteria and the recent Medfly finding described above, we are amending § 301.78-3 by expanding the current quarantined area in Hillsborough County, FL, and adding portions of Manatee and Polk Counties, FL, to the list of quarantined areas. The resulting quarantined areas are described in the rule portion of this document.

Emergency Action

The Administrator of the Animal and Plant Health Inspection Service has determined that an emergency exists that warrants publication of this interim rule without prior opportunity for public comment. Immediate action is necessary to prevent the Medfly from spreading to noninfested areas of the United States.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendment we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This action amends the Medfly regulations by expanding the current quarantined area in Hillsborough County, FL, and adding areas in Manatee and Polk Counties, FL, to the list of quarantined areas. The regulations restrict the interstate