(B) The substitution plan shall contain a step-by-step description of how production will be monitored; a complete description of the records that will be maintained for the commercial poultry substituted for the donated poultry and the disposition of the donated poultry delivered; and how the substitution will be tracked for the purpose of monthly reporting to the State distributing agencies. Poultry substitution shall not be subject to the 100-percent yield requirement; however, the AMS Grading Service must verify processing yields. Should a processor choose to have all production of a specific end product, identified by name and product code, produced under AMS grading, then the label ''Contains Commodities Donated by the United States Department of Agriculture. This Product Shall Only Be Sold to Eligible Recipient Agencies'' shall not be required. Finished poultry end products that have not been produced under AMS grading supervision may not be substituted for finished commodity end products.

* * * * *

(g) * * * As with the processing of donated poultry into end products, AMS graders must monitor the processing of any substituted commercial poultry to ensure that program integrity is maintained. * * *

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Dated: October 16, 2002.

Roberto Salazar,

Administrator, Food and Nutrition Service.

[FR Doc. 02–26874 Filed 10–22–02; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 305 and 319

[Docket No. 98–030–4]

RIN 0579–AA97

Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are establishing regulations providing for use of irradiation as a phytosanitary treatment for fruits and vegetables imported into the United States. The irradiation treatment provides protection against fruit flies and the mango seed weevil. This action provides an alternative to other 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.

EFFECTIVE DATE: October 23, 2002.

FOR FURTHER INFORMATION CONTACT: Dr. Inder P. Gadh, Import Specialist, Phytosanitary Issues Management, PPQ, APHIS, 4700 River Road Unit 140, Riverdale MD 20737–1236; (301) 734–5210.

SUPPLEMENTARY INFORMATION:

Background

In response to growing commercial interest in the use of irradiation as a treatment for agricultural products, the Animal and Plant Health Inspection Service (APHIS) has been developing policies for evaluating irradiation methods and 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.

In a proposed rule published in the **Federal Register** on May 26, 2000 (65 FR 34113–34125, Docket No. 98–030–1), we proposed a framework for the use of phytosanitary irradiation treatments for imported fruits and vegetables, and proposed specific standards for an irradiation treatment for fruit flies and the mango seed weevil (*Sternochetus mangiferae* (Fabricus), formerly known as *Cryptorhynchus mangiferae*) in imported fruits and vegetables. We solicited comments concerning our proposed rule for a period of 60 days, ending July 25, 2000. On August 4, 2000, we published a **Federal Register** notice that reopened and extended the comment period until August 21, 2000 (65 FR 47908, Docket No. 98–030–2). By the end of this comment period we received 2,212 comments, including many form letters and form postcards.

The various issues raised in these comments are discussed below by topic.

Comments Outside the Scope of APHIS' Authority

Approximately 2,000 of the comments we received on the proposed rule were a form letter, or slight variations of the form letter. In addition to comments addressing the proposed rule, discussed below, these form letters raised several issues that concern matters under the regulatory authority of other Federal and State agencies, not APHIS. We do not intend to reopen debate over matters that have been resolved through rulemaking by other agencies that have primary authority in these areas.

For example, one concern expressed is that irradiation will make foods unsafe to eat. The Food and Drug Administration (FDA) has primary regulatory responsibility for ensuring that approved irradiation doses do not render foods unsafe to eat. FDA regulations (21 CFR 179.26) establish a limit of 1.0 kilogray for disinfestation of arthropod pests in food. None of the irradiation doses contained in our rule exceed one quarter of this approved safe dose limit. A similar concern is whether irradiation could generate harmful chemicals from the cartons in which fruits and vegetables are irradiated. FDA has addressed safe packaging materials in 21 CFR 179.26, where it specifically allows wax-coated paperboard, the common carton type for fruits and vegetables.

Other comments suggested that irradiation facilities are inherently unsafe, and that workers and the public may be exposed to dangerous levels of radiation as the result of accidents at the plants or during transport of radioisotopes to and from plants. The Nuclear Regulatory Commission, the Occupational Safety and Health Administration, and the United States Department of Transportation have the primary regulatory responsibility for issues including irradiation facility construction, operation, employee and public safety, and transportation of

radioisotopes. Their requirements in these areas were established through public rulemaking by the respective agencies.

Many comments also stated that irradiation would reduce the nutritional value of fruits and vegetables, particularly through vitamin depletion, and could also mask the effects of spoilage. Again, regulation of these matters is outside the scope of the current rulemaking and outside the statutory authority of APHIS. However, on these points we do note for the record the following information from the August 2000 report by the United States General Accounting Office, ''Food Irradiation: Available Research Indicates That Benefits Outweigh Risks'' (GAO/RCED–00–217):

> There is also some vitamin loss associated with irradiation—with certain vitamins, such as thiamin (B1), ascorbic acid (C), and alpha-tocopherol (E)—more affected by irradiation than others. However, according to the Institute of Food Technologists, it is highly doubtful that there would ever be any vitamin deficiency resulting from eating irradiated food. For example, thiamin is the most radiation-sensitive, water-soluble vitamin. With regard to this vitamin, the American Dietetic Association's position statement on food irradiation notes that FDA evaluated an extreme case in which all meat, poultry, and fish were irradiated at the maximum permissible dose under conditions resulting in the maximum destruction of thiamin. Even in these circumstances, the average thiamin intake was above the Recommended Dietary Allowance, leading FDA to conclude that there was no deleterious effect on the total dietary intake of thiamin as a result of irradiating foods. In its 1980 evaluation of food irradiation, the Joint Expert Committee convened by FAO, WHO, and IAEA concluded that irradiation caused no special nutritional problems in food. Another meeting of experts in 1997—organized by the same three international organizations—concluded that even high doses of irradiation (*i.e.*, over 10 kGy) would not result in nutrient losses that could adversely affect a food's nutritional value.
>
> Irradiation cannot reverse the spoilage process—the bad appearance, taste, and/or smell will remain the same after irradiation. In addition, current regulations do not allow food processors to use doses of irradiation on meat, poultry, fruits, and vegetables that would be high enough to sterilize extremely contaminated food. If a processor attempted to use a sterilization dose on many of these products, the odor, flavor, taste, and texture would be seriously impaired and the consumer would reject such products.

APHIS Should Use Treatments and Procedures Other Than Irradiation To Control Pests

Numerous commenters stated that APHIS should not employ irradiation as a treatment but should instead use other treatments and procedures to prevent the introduction of dangerous plant pests associated with imported fruits and vegetables. They stated that these other methods were preferable to the human health risks and environmental effects the commenters believe are associated with irradiation. The suggested alternatives included fumigation with methyl bromide, cold treatment, heat treatment, pressure treatment, controlled atmosphere treatments altering carbon dioxide concentrations, and several developing technologies such as use of laser ultraviolet light pulses. Some commenters also suggested that APHIS should only allow articles to be imported from areas free from significant pests.

We have not made any changes to the rule in response to these comments. Again, we emphasize that importers are free to choose other treatments authorized by the regulations in lieu of irradiation. The reason that irradiation may be attractive to certain importers, particularly those importing fresh tropical fruits from fruit fly-infested regions, is that irradiation allows fruits of higher quality to be imported. Alternative heat, cold, and fumigation treatments often cause unacceptable phytotoxicity (damage to the fruits). Also, these alternative treatments often must be used on fruit harvested before it is fully ripe. The irradiation alternative allows importers to sell riper, more valuable fruit, with less damage.

In authorizing irradiation treatments, we have considered both the efficacy and the environmental effects of irradiation compared to other treatments already authorized by our regulations. The irradiation treatments in the final rule are effective against the listed plant pests. As discussed below, an environmental assessment and finding of no significant impact have been prepared for this rule, documenting the conclusions that the irradiation methods in this rule would not present a risk of introducing or disseminating plant pests, would have environmental effects that are substantially less than those of some other authorized treatments, and would not have a significant impact on the quality of the human environment.

It is true that several technologies under development may also provide effective treatments for various plant pests (*e.g.*, pressure treatments, controlled atmospheres, and laser ultraviolet light pulses). To date, we have not seen conclusive scientific documentation that establishes standard methodologies for these treatments, or that demonstrates that these treatments effectively control pests of concern in fruits and vegetables subject to APHIS regulations. APHIS is always willing to evaluate petitions to add new treatments to our import regulations. Petitioners should submit a detailed description of the methodology and standards of the treatment to be evaluated, and should include any scientific studies that document the effectiveness of the treatment and related issues (*e.g.*, quality effects on treated articles).

Prohibition of Irradiation Facilities in Southern States

In the proposed rule, § 305.2(b) provided that irradiation could be conducted prior to the arrival of articles in the United States, or after arrival, but limited 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. We proposed that irradiation facilities could 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. We proposed 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.

Four commenters stated that this restriction should be dropped. They stated that the restriction was unnecessary because imported shipments could be successfully safeguarded to prevent the escape of pests between the time the articles arrive and the time they are irradiated to destroy any pests associated with them. One commenter specifically suggested that in lieu of prohibiting irradiation in southern States, APHIS could impose stringent packaging requirements to prevent the escape of pests, such as plastic shrouding, banding of boxes, insect-proof screening, and additional labeling to prevent misrouting of articles. Another commenter described planned operating procedures for an irradiation facility to operate at a southern port of arrival. These procedures would subject containers arriving at the port to a sanitizing wash upon arrival, then move the unsealed containers directly into the irradiation facility before they are opened. The facility would have insect suppression systems to prevent the escape of insects, including solid walls separating untreated product from treated product. Another commenter stated that an irradiation facility in

Florida had already demonstrated the ability to move high-risk fruits and vegetables into the facility without escape of pests, treat them, and move them to their final destinations in Texas and California without reinfestation. That commenter submitted as evidence the protocols for moving and irradiating guavas, mangos, and sweet potatoes.

These commenters, in addition to arguing that irradiation facilities could safely operate in southern States, maintained that severe business and economic losses would result from prohibiting irradiation in southern States. They stated that this action would prevent the most logical ports from accepting shipments of fruits and vegetables from South America and Mexico. They also noted that the South has a large demand for the types of fresh fruits and vegetables that would enter in accordance with the rule. These commenters also noted that southern ports are currently allowed to import a large volume of fruits and vegetables that must be treated after arrival with treatments other than irradiation—*e.g.*, cold treatment, or fumigation with methyl bromide—and that the rule would be inconsistent to allow one kind of trade but not the other.

After careful consideration of these comments, we have decided that allowing irradiation facilities in all southern States under the requirements of the proposed rule, or under safeguards described in general terms by the commenters, would permit an unacceptable risk that fruit fly populations could become established and flourish in the southern climate, and therefore we are not changing the proposed general prohibition of irradiation facilities in southern States although, as discussed below, we are allowing irradiation facilities to be established at three ports in southern States if the facilities meet special conditions. The commenters requesting us to allow irradiation facilities in other southern States make strong arguments that there are notable business advantages related to certain port locations and established trade patterns for imported fruits and vegetables. However, our primary consideration must be the risk of introduction and establishment of dangerous plant pests.

The commenters argue that importing fruit fly host materials from fruit fly-infested regions for irradiation in southern States would be no riskier than other importations (and interstate movements) that are currently allowed. However, the examples they cite are not completely relevant. In the case of the Florida irradiation facility that irradiates guavas, mangos, and sweet potatoes for movement to Texas and California, the irradiated articles are of domestic origin. While they may be exposed to the Caribbean fruit fly, which is established in certain parts of Florida, they do not represent a risk of spreading exotic species of fruit flies. Also, even the risks associated with Caribbean fruit fly have become a concern to other States. In its own comment on the proposed rule, the California Department of Food and Agriculture expressed concern over the number of live Caribbean fruit fly larvae emerging from guavas irradiated in Florida, and was considering developing a quality control program for such fruit and reviewing its policy regarding the acceptance of heavily infested irradiated fruit from Florida. The other pests for which these articles are irradiated in Florida (weevils and surface pests) do not have the pest risk potential represented by exotic fruit flies. The argument that allowing this facility to irradiate imported fruit fly host material would not increase risks over the level of its current operations is therefore unconvincing.

We also disagree with the argument that southern ports are currently allowed to import a large volume of fruits and vegetables that must be treated after arrival with treatments other than irradiation—*e.g.*, cold treatment, or fumigation with methyl bromide—and that this justifies allowing irradiation in all southern States. Generally, the articles allowed to be imported into southern ports for fumigation treatment upon arrival are not high-risk fruit fly host materials; when such articles are allowed to be imported, they must be treated prior to arrival. Some higher-risk articles (*e.g.*, citrus, apples, grapes, and pears) are allowed to be imported into three southern ports (Wilmington, NC; Gulfport, MS; and the Atlanta, GA, airport) for cold treatment after arrival. Unlike northern ports, at least two of these three ports (Gulfport and Atlanta) do not have sufficient biological barriers, including climatic conditions, to prevent the introduction and establishment of fruit flies and other insect pests that could escape from shipments of imported fruit after arrival in the United States. Cold treatment after arrival is allowed at these three ports because APHIS has imposed special conditions to mitigate the risk of the introduction of fruit flies and other insect pests into the United States (*see* 7 CFR 319.56–2d(b)(5)(iv), (vi), and (vii)).

The special conditions appropriate for allowing cold treatment after arrival would also be sufficient to safely allow irradiation treatment after arrival, although several requirements for cold treatment facilities (*e.g.*, back-up cooling systems and cold holding rooms) would not be needed for irradiation facilities at these ports. Therefore, we are changing this final rule to allow irradiation facilities to be located at the ports of Gulfport, Wilmington, and Atlanta. We are accomplishing this change by adding a footnote to § 305.2(b), which lists States where facilities may be located, to read as follows: ''Irradiation facilities may be located at the maritime ports of Gulfport, MS, or Wilmington, NC, or the airport of Atlanta, GA, if the following special conditions are met: The articles to be irradiated must be imported packaged in accordance with paragraph (g)(2)(i)(A) of this section; the irradiation facility and APHIS must agree in advance on the route by which shipments are allowed to move between the vessel on which they arrive and the irradiation facility; untreated articles may not be removed from their packaging prior to treatment under any circumstances; blacklight or sticky paper must be used within the irradiation facility, and other trapping methods, including Jackson/methyl eugenol and McPhail traps, must be used within the 4 square miles surrounding the facility; and the facility must have contingency plans, approved by APHIS, for safely destroying or disposing of fruit.''

These special conditions are derived from the special conditions in § 319.56–2d(b)(5) that are required for cold treatment facilities in Wilmington, Gulfport, and Atlanta. The purposes of the conditions are as follows.

Insect-proof packaging; no removal from packaging prior to treatment. These requirements guard against the possible escape of adult, larval, or pupal fruit flies or other pests.

Approval of the route by which shipments are allowed to move between the vessel on which they arrive and the irradiation facility. This requirement allows APHIS to ensure the articles are not moved through areas containing crops or wild plants that are good host material for fruit flies, and to ensure timely, low-risk delivery to the irradiation facility.

Fruit fly attractants and traps in the irradiation facility and surrounding areas. The dual purpose is to both kill escaped fruit flies and to reveal their presence so further control efforts can be planned.

Contingency plans for safely destroying or disposing of fruit. If irradiation operations are delayed due to equipment failure or for other reasons, APHIS may order articles

destroyed to avoid risks that pests might escape them while they are in storage.

We are not changing the final rule to allow irradiation at other ports in southern States at this time. Post-arrival cold treatments at the ports of Wilmington, Gulfport, and Atlanta were initially allowed in the mid-1990s after APHIS evaluated detailed petitions from port authorities, State governments, and business interests who worked jointly to develop detailed proposals for the siting, operations, and safeguarding of cold treatment facilities at these ports. Requests to allow irradiation at other southern ports would have to be evaluated in a similar manner. In each case we would have to thoroughly evaluate the risk situation of the suggested port, including the individual port's latitude, microclimate, immediate host availability, and past fruit fly infestations. After such evaluation, if APHIS determines special conditions that would allow post-arrival irradiation treatment to occur without risk of spreading pests, we would initiate rulemaking to allow such treatment at the designated ports.

Therefore, with the exception noted above for Wilmington, Gulfport, and Atlanta, this final rule includes the requirement of the proposal that irradiation facilities in southern States may not treat imported articles in accordance with the regulations. However, we welcome detailed petitions from businesses working in concert with port authorities and State governments who believe that post-arrival irradiation treatment facilities can safely operate at particular southern ports.

Recommended Doses

The proposed rule, in § 305.2, set forth the following irradiation doses:

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

Scientific name	Common name	Dose (gray)
(1) *Bactrocera dorsalis*	Oriental fruit fly	250
(2) *Ceratitis capitata*	Mediterranean fruit fly	225
(3) *Bactrocera cucurbitae*	Melon fly	210
(4) *Anastrepha fraterculus*	South American fruit fly	150
(5) *Anastrepha suspensa*	Caribbean fruit fly	150
(6) *Anastrepha ludens*	Mexican fruit fly	150
(7) *Anastrepha obliqua*	West Indian fruit fly	150
(8) *Anastrepha serpentina*	Sapote fruit fly	150
(9) *Bactrocera tryoni*	Queensland fruit fly	150
(10) *Bactrocera jarvisi*	(No common name)	150
(11) *Bactrocera latifrons*	Malaysian fruit fly	150
(12) *Sternochetus mangiferae* (Fabricus)	Mango seed weevil	100

Six commenters made comments suggesting changes to these dose rates. Four of these commenters suggested specific dose rate changes, and two addressed the need for research on dose rates more generally. Several commenters drew attention to the statement in the proposed rule (pp. 34113–34114) that ''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.'' Three commenters stated that APHIS did not set doses at the lowest level that will prevent adult emergence and cited research reports to support their positions.

The commenters who suggested specific changes to doses suggested the following doses for the final rule:

Scientific name	Common name	Proposed dose (gray)	Dose suggested by commenters
(1) *Bactrocera dorsalis*	Oriental fruit fly	250	150
(2) *Ceratitis capitata*	Mediterranean fruit fly	225	150
(3) *Bactrocera cucurbitae*	Melon fly	210	150
(4) *Anastrepha fraterculus*	South American fruit fly	150	100
(5) *Anastrepha suspensa*	Caribbean fruit fly	150	100
(6) *Anastrepha ludens*	Mexican fruit fly	150	100
(7) *Anastrepha obliqua*	West Indian fruit fly	150	100
(8) *Anastrepha serpentina*	Sapote fruit fly	150	100
(9) *Bactrocera tryoni*	Queensland fruit fly	150	100
(10) *Bactrocera jarvisi*	(No common name)	150	100
(11) *Bactrocera latifrons*	Malaysian fruit fly	150	100
(12) *Sternochetus mangiferae* (Fabricus)	Mango seed weevil	100	300

One commenter stated that the new doses were supported by ''numerous sound science based studies,'' but did not identify specific studies. Two commenters referred to research reports contained in ''Proceedings of the Final Research Coordination Meeting on Use of Irradiation as a Quarantine Treatment of Food and Agricultural Commodities'' (IAEA 1992) and ''Report of ICGFI Task Force on Irradiation as a Quarantine Treatment of Fresh Fruits and Vegetables'' (ICGFI 1991). These studies support the proposition that a 150 gray treatment for *B. dorsalis, B. cucurbitae,* and *C. capitata* is effective in preventing emergence of adult flies.

Another commenter cited studies by Hallman (1999), Bustos *et al.* (1992), and Gould & von Windeguth (1991) to support doses of 100 gray to treat for *A. suspensa, A. ludens, A. obliqua, A. serpentina, B. jarvisi,* and *B. tryoni.* This commenter also stated that the research suggests that the doses of 250 gray for *B. dorsalis* and 225 gray for *C. capitata*

may be too high, but suggested that APHIS seek further research to demonstrate this rather than changing those doses at this time. This commenter also suggested that the dose for mango seed weevil, *S. mangiferae*, should be raised to 300 gray, because the 100 gray dose was based on two limited studies that did not fully evaluate the efficacy of irradiating the weevils in mangoes, rather than in laboratory vials, and due to the extremely high rate of infestation of many foreign mangoes by the seed weevil.

Another commenter cited recent research indicating that a dose of 100 gray prevents adult emergence of *A. ludens, A. obliqua,* and *A. serpentina*, and that a dose of 150 gray does so for *C. capitata*. The research cited showed no adult emergence at these doses after study of more than 100,000 irradiated third instar larvae in mangoes.

In addition to suggesting that smaller doses may be effective in controlling fruit flies, several commenters stated that the proposed doses, as applied in commercial operation, would cause an unacceptably high level of damage to the quality of fresh fruit. These commenters noted that commercial irradiators treating large lots often must expose some of the lot (*e.g.,* outer layers) to two to three times the minimum dose in order to ensure that the entire lot receives at least the minimum dose. Therefore, some of the fruit treated to a minimum dose of 150 gray could receive a dose of up to 450 gray, a dose that significantly reduces the quality of some fruits. A minimum dose of 250 gray (proposed for *B. dorsalis*) would result in some of the lot being exposed to up to 750 gray, a level that would reduce most fruits to an unsaleable quality. These commenters also noted that there is a direct relationship between dose and cost of treatment; the higher the dose, the greater the cost; and suggested that it might not be economically feasible for commercial irradiators to treat fruit using the proposed doses.

Based on these comments concerning doses, we have decided to increase the dose for mango seed weevil from 100 gray to 300 gray, and to leave all the other doses at their proposed levels. We have reexamined research on irradiation as a means to control seed weevils, and the preponderance of it supports using a higher dose than the 100 gray we proposed. The only research that found 100 gray to be effective against mango seed weevil was a limited study involving a very few insects; other research by Heather and Corcoran (1990) [1], Jessup and Rigney (1990) [2], and Follett [3] found that a dose in the 300 gray range was necessary to effectively control the weevil.

The comments suggesting lowered doses for other pests, and the research supporting these comments, may have merit, but such research must be carefully evaluated and verified before we lower doses below the proposed levels, which we know are effective. APHIS, in cooperation with the Agricultural Research Service and others, will evaluate the lower doses recommended by commenters. If we determine that any or all of the recommended lower doses are effective, we will initiate rulemaking in the future to reduce the doses. However, this evaluation process will take time, and the current final rule maintains the proposed higher doses so that irradiation treatments may occur while this evaluation is underway.

Barriers Between Treated and Untreated Articles in Irradiation Facilities

Several commenters addressed the possibility that, while articles are in an irradiation facility, pests might move from articles that have not yet been irradiated to articles that have been irradiated. If this happens, irradiated articles would pose a risk of spreading these pests. They noted that if the irradiation facility is outside the United States, this risk is addressed by the proposed requirement that articles must be in insect-proof cartons before, during, and after irradiation. However, the proposal did not require insect-proof cartons at irradiation facilities in the United States. Also, while the proposed physical layout for irradiation facilities, with physically separate locations for treated and untreated articles (§ 305.2(e)(2), would prevent mixing of articles, it would not prevent the self-movement of pests from untreated articles to treated articles in the facility. The proposal only required that facility areas for untreated and treated articles ''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.'' While the proposal stated that normal business practices result in material moving through a facility quickly for cost reasons, and that untreated material would not remain in a facility long enough for adult flies to emerge from untreated materials and move to treated materials, these commenters stated that unforseen delays and processing backlogs could sometimes allow enough time for pests to move from untreated to treated articles. They suggested that for this reason, irradiation facilities in the United States should be required either to use insectproof cartons, or to have a solid barrier impervious to fruit flies between areas of the facility where untreated articles are kept and areas of the facility where treated articles are kept.

We have not made any change based on these comments because there is only a slight risk of this scenario occurring, because it is extremely improbable that larvae could crawl from the untreated to the treated area of the facility, and articles do not remain in the untreated section long enough for flies to hatch and move to the treated area. Section 305.2(c) addresses even these slight risks, by stating that in the compliance agreement a facility must sign with APHIS, ''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 drawing up that compliance agreement, we will consider on a case-by-case basis for each facility whether safeguards are needed to prevent the escape or movement of pests at that facility.

Monitoring of Foreign Irradiation Facilities by Foreign Plant Protection Organizations and by APHIS

Several commenters suggested that effective monitoring of operations at foreign irradiation facilities was crucial to ensure that treatments were safe and effective. These commenters pointed out that in some countries the national plant protection organization could provide most of this monitoring, while in others APHIS would have to provide most of the monitoring, depending on different situations in different countries. They suggested that the section of the rule dealing with monitoring should be flexible enough to let APHIS vary its level of monitoring as needed, based on the infrastructure and capabilities of plant protection organizations in different countries. They also suggested

[1] Heather, N.W., and Corcoran, R.J. ''Effects of ionizing energy on fruit flies and seed weevil in Australian mangoes''. Proceedings of the IAEA/FAO Research Coordination Meeting on the Use of Irradiation as a Quarantine Treatment of Food and Agricultural Commodities, Kuala Lumpur, Malaysia, August, 1990.

[2] Jessup, A.J., and Rigney, C.J. ''Gamma irradiation as a commodity treatment against Dacus tryoni, Queensland fruit fly, in fresh fruit.'' Proceedings of the IAEA/FAO Research Coordination Meeting on the Use of Irradiation as a Quarantine Treatment of Food and Agricultural Commodities, Kuala Lumpur, Malaysia, August, 1990.

[3] Dr. Peter Follett, Agricultural Research Service, USDA. Personal communication (1999).

that the activities that foreign plant protection services will conduct to enforce the regulations and monitor compliance should be recorded in an agreement between the foreign plant protection service and APHIS.

We agree with this comment, and have decided that the monitoring section of the rule should allow APHIS to target its monitoring as needed and provide the appropriate level of monitoring, ranging from intermittent monitoring of operations and inspection of records to a continual APHIS presence at facilities and regular inspection of untreated and treated articles for pests. We also believe that providing this level of monitoring may require APHIS to arrange for foreign plant protection services to deposit monies into a trust fund to reimburse APHIS for services, as is common practice under many other APHIS import regulations (*e.g.,* importing Fuji apples from Japan and the Republic of Korea under § 319.56–2cc, or importing Hass avocados from Mexico under § 319.56–2ff). We also agree that the activities of foreign plant protection services in support of the regulations should be recorded in a work plan that the foreign plant protection service submits to APHIS.

Supplemental Proposed Rule

Because the issues of appropriate levels of monitoring, foreign plant protection service work plans, and another issue mentioned by commenters—carton irradiation indicators, were not specifically raised in the proposed rule, we published a supplemental proposed rule to seek public comment on these issues. That supplemental proposed rule was published in the **Federal Register** on March 15, 2002 (67 FR 11610–11614, Docket 98–030–3). We accepted public comments on the supplemental proposed rule for 30 days, ending April 15, 2002. We received 67 comments during that period.

In that supplemental proposed rule, we proposed changing the monitoring section of the rule to allow APHIS to provide an appropriate level of monitoring at irradiation facilities depending on the situations in different countries, to establish two kinds of work plans to document requirements and activities, and to establish trust funds with national plant protection organizations to reimburse APHIS for its expenses.

These changes reflect our position that APHIS should sign work plans with foreign plant protection services to clearly state what regulatory requirements and levels of inspection, monitoring, and other activities apply to importation of irradiated articles into the United States and into the signatory foreign country, and that APHIS should be able to target its monitoring as needed, ranging from intermittent monitoring of operations and inspection of records to a continual APHIS presence at facilities and regular inspection of untreated and treated articles for target and nontarget pests.

With respect to the work plans, the supplemental proposed rule provided, in support of the equivalence principle, that APHIS and each foreign plant protection service will sign an irradiation treatment framework equivalency work plan that clearly states what legislative, regulatory, and other requirements must be met, and what monitoring and other activities must occur, for irradiated articles to be imported into the United States, or into the foreign country.

Of the approximately 10 comments that addressed this proposed revision of proposed § 305.2(f), most supported the changes. One commenter addressed the language in proposed § 305.2(f)(1) that would require the framework equivalency work plan to include ''citations for any requirements that apply to the importation of irradiated fruits and vegetables.'' The commenter pointed out that some countries may not develop or legislate original requirements regarding irradiation, but may rely on and cite irradiation standards developed by international bodies such as the International Consultative Group on Food Irradiation, the International Plant Protection Convention, and others. APHIS is aware of this, and believes no change to the proposed language is needed. The framework equivalency work plan can cite whatever requirements the respective countries apply to irradiated fruits and vegetables, whether they are laws or regulations of that country or international guidelines or standards.

One commenter addressed the statement in proposed § 305.2(f)(1)(ii) that the framework equivalency plan must describe ''the type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated fruits and vegetables.'' This commenter stated that inspection and monitoring of irradiation processing should not differ significantly from other treatment methods, *e.g.*, heat or cold treatments, fumigation, or controlled atmosphere treatments.

APHIS does not believe any change is necessary in regard to this comment. The proposed language does not set any required level for inspection and monitoring activities; it merely asks each country to state the level of such activities it chooses to require in the framework equivalency plan. We do not agree that all types of treatment necessarily require the same level of monitoring and inspection to verify that they are effective. The level required depends on the nature of the treatments and their technical complexity, including the number of critical control points to be monitored.

This commenter also noted that the framework equivalency plan is silent on the role of the irradiation facility, and suggested the facility should be involved in developing framework equivalency plans because facilities bear the major responsibility for making effective monitoring possible.

We do not believe any change is needed in response to this comment. The point of the framework equivalency plan is to document consistency in national requirements for importation of irradiated fruits and vegetables. The proposed regulations present no barrier to consultations between a foreign plant protection service and an irradiation facility during development of a framework equivalency plan, but it is not APHIS' place to require foreign governments to have such consultations when developing their import requirements. With regard to documenting the role and specific responsibilities of irradiation facilities under our regulations, we note that proposed § 305.2(d) requires that both a compliance agreement and an annual work plan be developed and signed by APHIS and the foreign irradiation facility.

One commenter objected to the trust fund agreement in proposed § 305.2(f)(3), stating that it is unnecessary for APHIS to send personnel to foreign countries to monitor irradiation processing. He stated that between the framework equivalency work plan and the facility preclearance work plan in proposed § 305.2(f), APHIS had set up a system where equivalency in national requirements existed, in terms of the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization. Article 4 of that Agreement states that ''Members shall accept the sanitary and phytosanitary measures of other members as equivalent, even if these measures differ from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary

or phytosanitary protection.'' If this situation applies, the commenter stated, ''it is more cost effective for both importing and exporting countries to establish and agree to the ''equivalency work plan,'' including the procedure for operation of irradiation facilities required for treating fruits and vegetables, than to continue to depend on inspection and monitoring of operation of quarantine treatments by officials from importing countries. Exporting countries *must* ensure that fruits are produced through Good Agricultural Practices (GAPs), and handled and processed or treated through proper protocols under Good Manufacturing Practices (GMPs) to be in compliance with the requirements of the importing countries. Each step in the production, handling, processing/ treatment *must* be certified by the competent authorities in importing countries. The final product must be certified by the national plant protection organization that proper quarantine treatment, *e.g.* irradiation, was done * * *.''

In response to this comment, APHIS understands that equivalency issues under the SPS Agreement are complex and evolving. First, we note that USDA collects funds for the foreign activities of its inspectors in accordance with specific statutory authority, 7 U.S.C. 7753(a), which states ''The Secretary may enter into reimbursable fee agreements with persons for preclearance of plants, plant products, biological control organisms, and articles at locations outside the United States for movement into the United States.''

Secondly, we disagree that, by jointly developing a framework equivalency work plan and a facility preclearance work plan, APHIS and the exporting country will demonstrate that equivalency exists. At most, developing these plans will help identify *to what degree* equivalency exists, and may also identify areas where the procedures and technical expertise of the exporting country do not meet the United States' ''appropriate level of sanitary or phytosanitary protection.'' Certainly, the level of inspection and monitoring performed by APHIS employees under the trust fund agreement will vary depending on the effectiveness—the equivalency—of the activities of the foreign plant protection service.

In developing the framework equivalency work plan—a joint activity—both APHIS and the exporting country will have the opportunity to negotiate the necessary or appropriate conditions to establish and run the program. In some cases, there may be concerns about whether the exporting country has adequate technical expertise, experience, and oversight capability to ensure an irradiation treatment program is conducted properly. In other cases, the host government may have more capability. This final rule does not preclude the exporting country from proposing alternative approaches or options for meeting any concerns we may have that might cause us to increase the level of activities by APHIS inspectors under the trust fund agreement. Also, the framework equivalency work plan will be subject to annual review, which allows for the possible reduction of oversight (and associated costs) as confidence grows in the program.

Thirdly, costs associated with implementing an inspection, treatment, or other safeguarding program are normal and expected in agricultural trade. The obligation in the SPS Agreement is that ''* * *any fees imposed for procedures related to control, inspection, and approval are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service'' (Annex C). In other words, APHIS should avoid inconsistent or discriminatory charges or fees, and we believe the final rule does this.

One commenter stated that the work plans and monitoring provisions in proposed § 305.2(f) are premature and are subject to challenge, vis-a-vis pending revisions to the two main General Standards of the Codex Alimentarius Commission that relate to food irradiation. If and when these standards are approved, they could become official WTO guidance addressing operational requirements at irradiation facilities, including dosimetry, recordkeeping, inventory control, inspections, and other matters. The commenter stated that any conflict between U.S. food standards and those of a WTO member nation could be challenged under the WTO's binding dispute resolution system.

We are making no change based on this comment. The fact that the Codex Alimentarius Commission is working on developing standards for the future does not provide any current basis for a challenge to our regulations. If and when international standards are ready for adoption, we will examine them to determine whether any of our regulations should be amended to be consistent with them. We also note that APHIS has consistently worked with bodies developing international guidelines for irradiation of fruits and vegetables, and we believe our final rule is consistent with the anticipated products of these bodies.

One commenter suggested a change to proposed § 305.2(h)(3), which read ''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.'' This commenter pointed out that much of the ASTM ''standards'' are actually guidelines that are meant to be flexible and adaptive, and to state that they ''must'' be followed is confusing. The commenter also noted that there are other authoritative sources similar to ASTM standards regarding dosimetry, such as standards developed by the National Institute of Standards and Technology, that are in wide use in U.S. and foreign nuclear industries.

We agree that the reference in proposed § 305.2(h)(3) was too definite and restrictive, and implied that the ASTM published precise dosimetry standards that all irradiation facilities could and must follow exactly. In fact, the ASTM describes its dosimetry guide as a document that ''covers the basis for selecting and calibrating dosimetry systems used to measure absorbed dose * * *. It discusses the types of dosimetry systems that may be employed during calibration or on a routine basis as part of quality assurance in commercial radiation processing of products. This guide also discusses interpretation of absorbed dose and briefly outlines measurements of the uncertainties associated with the dosimetry. The details of the calibration of the analytical instrumentation are addressed in individual dosimetry system standard practices * * *. This guide should be used along with standard practices and guides for specific dosimetry systems and applications covered in other standards.''

In fact, the ASTM standards for dosimetry describe basic principles, effective techniques, and best practices, but do not provide absolute or mandatory standards for dosimetry systems. To recognize this, we are changing the statement in § 305.2(h)(3) to read as follows: ''When designing the facility's dosimetry system and procedures for its operation, the facility operator must address guidance and principles from American Society for Testing and Materials (ASTM) standards or an equivalent standard recognized by the Administrator.''

Irradiation Indicators and Tests To Identify Irradiated Fruit

Several commenters on the original proposed rule suggested that we should

require that prior to irradiation, indicators should be attached to cartons of articles. These indicators would change color, or undergo some other obvious change, when exposed to irradiation in the required dose range for regulated articles. The commenters stated that these indicators would be a very useful safeguard and could be used by enforcement personnel and others as a quick check to confirm that a particular carton had in fact been exposed to the required level of radiation. Commenters identified several devices and dye-impregnated labels that react to radiation in the 150–250 gray range.

Because we did not propose to require any such indicators or tests in the proposed rule, we discussed their use in the supplemental proposed rule. In the supplemental proposed rule, we proposed to change the paragraph addressing packaging, § 305.2(g)(1), to state that ''each carton must bear an indicator device, securely attached prior to irradiation, that changes color or provides another clear visual change when it is exposed to radiation in the dose range required by this section for the pests for which the articles are being treated.''

We received more than 20 comments on this proposed change. Several were mildly supportive of using carton indicators, but the large majority of comments opposed the requirement for numerous technical, operational, and cost-benefit reasons. Several commenters cited the report, ''Standardized methods to verify absorbed dose in irradiated food for insect control,'' published in 2001 by the International Atomic Energy Agency, IAEA, Vienna, IAEA–TECDOC–1201. The commenters stated that the findings of that report indicated that, at present, color indicator devices are not suitable and not reliable to be used in phytosanitary applications and should not be used until such devices are further developed and are thoroughly tested for reliability.

Other commenters cited the document ASTM Standard E 1539–98, ''Standard Guide for Use of Radiation-Sensitive Indicators.'' Section 7.3 of that document states: ''Some irradiation or storage conditions may result in false positive or negative observations. For these reasons, indicators should not be used as a criterion for product release. Also, external environmental influences may make the interpretation of the indicators meaningless outside the irradiation facility unless appropriate controls are used.''

One commenter cited several additional research articles [4] that evaluate the effectiveness, sensitivity, and vulnerability to environmental effects of irradiation indicators.

Several commenters noted that the few indicators currently on the market were not sensitive enough to properly document the proposed dose ranges of 100 to 250 gray. They noted that the margin of error for such indicators appeared to be about 100 gray—meaning that an indicator designed to change color at a dose of 250 gray might change at a dose as low as 150 gray, or not change until it received a dose of 350 gray. These commenters noted that if irradiation facilities concentrate on indicator color change as a measure of success, they could subject some articles to unnecessarily high doses, or even pass some articles that received less than the required doses.

Several commenters suggested that APHIS should concentrate on ensuring that irradiation facilities conduct and document proper and effective dosimetry programs and not require carton indicators unless and until they are proven reliable, useful, and cost-effective at a later date. They suggested that inspectors at the port of entry, if they find insects or larvae in an irradiated shipment or have other questions about the adequacy of the irradiation, could use the required labeling and documentation to check on the treatment of that shipment—*e.g.*, by matching carton lot numbers from the port with carton lot numbers in the facility's records. Inspectors could readily verify with the facility operator that a particular shipment had been irradiated, and could also check APHIS monitoring records for that facility. Given modern communications and databases, such verification would not unduly delay release of shipments at ports.

Other commenters took issue with a statement in the economic analysis for the supplemental proposal that use of indicators would increase the price of imported articles by only ''a few cents per pound.'' These commenters pointed out that, even if this is true, the cost of irradiating articles at some facilities could be as low as 5 cents per pound, and increasing this cost to 8 cents by requiring indicators amounted to a 60 percent cost increase for treatment. They also noted that a price differential of 3 cents per pound could be a critical disadvantage in some market situations.

We have carefully analyzed all the data and opinions submitted recommending against the indicator requirement, and we have decided not to require indicators at this time. While we believe that a conceivable indicator could be employed as a possible cross-check at ports of entry, apparently there is no such indicator that is: (1) Currently available at low cost; (2) validated to be sensitive and reliable in the appropriate dose ranges; and (3) validated to be resistant to false positives and false negatives caused by environmental effects. We also concur with commenters that, at least during the early implementation of this program and the first operations of irradiation facilities under the regulations, it is important to concentrate on effective dosimetry programs and recordkeeping at facilities, and effective communications between APHIS inspectors and facilities to backtrack treatment records for individual shipments, rather than attempting to use problematic indicator technologies.

One commenter wrote, in support of requiring indicators, that it was a manufacturer of luminescence technology devices that were sensitive to irradiation in the dose ranges APHIS proposed. While these indicators do not change color in a manner visible to the naked eye, their state change after irradiation can be read by an inexpensive device similar to a barcode scanner. This commenter claimed that such indicators have advantages in terms of cost, resistance to environmental effects, and counterfeit resistance.

While such devices are not consistent with the type of indicator APHIS proposed—which was for an indicator ''that changes color or provides another clear visual change''—APHIS will consider such devices, along with other types of indicator technology, in its future consideration of whether to require indicators. We wish to emphasize that we welcome suggestions regarding ways indicators might be used effectively, and technical descriptions of available indicators. Also, since irradiation facilities in foreign countries,

[4] Ehlermann, D.A.E. (Federal Research Centre for Nutrition, Karlsruhe (DE). Inst. of Process Engineering), ''Validation of a label dosimeter for food irradiation applications by subjective and objective means,'' Appl. Radiat. Isot.; v. 48(9), p. 1197–1201; 1997.

Ehlermann, D.A.E. (Federal Research Centre for Nutrition, Karlsruhe (Germany). Inst. of Process Engineering), ''Validation of a label dosimeter with regard to dose assurance in critical applications as quarantine control,'' International Atomic Energy Agency, IAEA; Vienna (Austria); 1999, p. 265–270; IAEA–TECDOC—1070; IAEA–SM–356/38.

International Atomic Energy Agency, ''Standardized methods to verify absorbed dose in irradiated food for insect control,'' IAEA, Vienna, 2001, IAEA–TECDOC–1201.

Razem, D. (Ruder Boskovic Inst., Zagreb (Croatia)), ''Dosimetric performance of and environmental effects on sterin irradiation indicator labels,'' Radiat. Phys. Chem.; v. 49(4) p. 491–495.

and the government agencies that regulate irradiation in those countries, ultimately bear a great deal of responsibility for ensuring that products are irradiated in accordance with APHIS requirements, we welcome any suggestions from those sources on the use of indicators or other methods for confirming that products were properly irradiated.

Other Comments on the Supplemental Proposed Rule

We received approximately 50 comments on the supplemental proposed rule that were similar to the 2000 form-letter comments we received on the original proposal. These comments generally raised issues that are outside the scope of the current rulemaking, such as the safety of irradiation facilities and the nutritional value of irradiated food.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed in this document.

Effective Date

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 an alternative to other currently approved treatments against fruit files and the mango seed weevil in fruits and vegetables, thus relieving restrictions. 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 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 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. 604, we have performed a final regulatory flexibility analysis regarding the effect of this rule on small entities. In the initial regulatory flexibility analysis in the proposed rule we stated that we did not have all the data necessary for a comprehensive analysis of the effects of this rule on small entities, and we invited comments concerning potential effects. In particular, we solicited data to help determine the number and kinds of small entities that may incur benefits or costs from implementation of this proposed rule. We did not receive any comments challenging our estimates of the number and kinds of small entities affected, although several comments did state that the additional cost of requiring carton indicators (a requirement removed from this final rule, as discussed elsewhere in this document) would have adverse impacts on both large and small importers.

Under the Plant Protection Act (7 U.S.C. 7701–7772), 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 rule will permit the treatment of imported fruits 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 are 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 must use an approved dosimetry system during treatment and keep records to verify effective irradiation. For irradiation after arrival, compliance agreements will 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 rule will 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 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 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 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.[5] 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 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.[6] 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.[7] 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 phase out required by the Clean Air Act.[8] 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 phase out 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 phase out 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.[9] 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 phase-out 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.

This rule will 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 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

[5] ''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.

[6] ''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**).

[7] 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).

[8] 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).*

[9] 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.

fruits and vegetables will depend upon the demand that develops for irradiation in relation to alternative treatments.

The economic effects of the changes adopted from the supplemental proposed rule result from the establishment of trust fund agreements to reimburse APHIS for its activities monitoring irradiation facilities in foreign countries. We are requiring that the inspection and monitoring activities performed by a foreign plant protection service at irradiation facilities located overseas be recorded in an agreement signed by the foreign service and APHIS. The purpose of the agreement is to ensure appropriate levels of inspection and monitoring at the facilities, thereby reducing any pest risk due to misunderstandings or shortcomings in the oversight of irradiation and related processes at facilities.

When a foreign plant protection service establishes a trust fund agreement to reimburse APHIS for expenses, that service may or may not pass along the cost of depositing those funds to producers in that country, depending on the service's funding mechanisms. If it passes along that cost to foreign producers, those producers will likely raise the price of fruits and vegetables exported to the United States to cover the costs. However, we expect that trust fund agreement costs to have a negligible effect on the prices paid by U.S. merchants and consumers for the imported produce.

The benefits of the trust fund agreements accrue because the agreements will increase the reliability of irradiation as a phytosanitary treatment. Thus, benefits are evaluated in terms of preventing potential economic losses in U.S. fruit and vegetable markets that could occur if pests should enter the United States with articles that were not properly irradiated because trust fund agreements to monitor treatments were not in effect. These benefits cannot be readily quantified. As an example, however, averting the costs associated with a single fruit fly outbreak in the United States would save more than the total costs for trust fund agreements over many years.

The major alternative to this 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 final rule contains information collection requirements, which have been approved by the Office of Management and Budget (*see* ''Paperwork Reduction Act'' below).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (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 been prepared for this rule. The assessment provides a basis for the conclusion that the irradiation methods 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 the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0155.

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, title 7, chapter III, of the Code of Federal Regulations is amended as follows:

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

PART 305—PHYTOSANITARY TREATMENTS

Sec.

Authority: 7 U.S.C. 7701–7772; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

§ 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.

Inspector. Any employee of the Animal and Plant Health Inspection Service or other person authorized by the Administrator to inspect and certify the plant health status of plants and products under this part.

§ 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)
(1) *Bactrocera dorsalis*	Oriental fruit fly	250
(2) *Ceratitis capitata*	Mediterranean fruit fly	225
(3) *Bactrocera cucurbitae*	Melon fly	210
(4) *Anastrepha fraterculus*	South American fruit fly	150
(5) *Anastrepha suspensa*	Caribbean fruit fly	150
(6) *Anastrepha ludens*	Mexican fruit fly	150
(7) *Anastrepha obliqua*	West Indian fruit fly	150
(8) *Anastrepha serpentina*	Sapote fruit fly	150
(9) *Bactrocera tryoni*	Queensland fruit fly	150
(10) *Bactrocera jarvisi*	(No common name)	150
(11) *Bactrocera latifrons*	Malaysian fruit fly	150
(12) *Sternochetus mangiferae* (Fabricus)	Mango seed weevil	300

(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[1], Kentucky, Louisiana, Mississippi1, Nevada, New Mexico, North Carolina1, 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 the amount of 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;[2]

(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, or some other means approved during certification to prevent reinfestation of articles and spread of pests;

(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) *Monitoring and interagency agreements.* Treatment must be monitored by an inspector. This monitoring will include inspection of treatment records and unannounced inspections of the facility by an inspector, and may include inspection of articles prior to or after irradiation. Facilities that carry out irradiation

[1] Irradiation facilities may be located at the maritime ports of Gulfport, MS, or Wilmington, NC, or the airport of Atlanta, GA, if the following special conditions are met: The articles to be irradiated must be imported packaged in accordance with paragraph (g)(2)(i)(A) of this section; the irradiation facility and APHIS must agree in advance on the route by which shipments are allowed to move between the vessel on which they arrive and the irradiation facility; untreated articles may not be removed from their packaging prior to treatment under any circumstances; blacklight or sticky paper must be used within the irradiation facility, and other trapping methods, including Jackson/methyl eugenol and McPhail traps, must be used within the 4 square miles surrounding the facility; and the facility must have contingency plans, approved by APHIS, for safely destroying or disposing of fruit.

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

operations must notify the Director of Preclearance, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236, of scheduled operations at least 30 days before operations commence, except where otherwise provided in the facility preclearance work plan. To ensure the appropriate level of monitoring, before articles may be imported in accordance with this section, the following agreements must be signed:

(1) *Irradiation treatment framework equivalency work plan.* The plant protection service of a country from which articles are to be imported into the United States in accordance with this section must sign a framework equivalency work plan with APHIS. In this plan, both the foreign plant protection service and APHIS will specify the following items for their respective countries:

(i) Citations for any requirements that apply to the importation of irradiated fruits and vegetables;

(ii) The type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated fruits and vegetables into that country; and

(iii) Any other conditions that must be met to allow the importation of irradiated fruits and vegetables into that country.

(2) *Facility preclearance work plan.* Prior to commencing importation into the United States of articles treated at a foreign irradiation facility, APHIS and the plant protection service of the country from which articles are to be imported must jointly develop a preclearance work plan that details the activities that APHIS and the foreign plant protection service will carry out in connection with each irradiation facility to verify the facility's compliance with the requirements of this section. Typical activities to be described in this work plan may include frequency of visits to the facility by APHIS and foreign plant protection inspectors, methods for reviewing facility records, and methods for verifying that facilities are in compliance with the requirements for separation of articles, packaging, labeling, and other requirements of this section. This facility preclearance work plan will be reviewed and renewed by APHIS and the foreign plant protection service on an annual basis.

(3) *Trust fund agreement.* Irradiated articles may be imported into the United States in accordance with this section only if the plant protection service of the country in which the irradiation facility is located has entered into a trust fund agreement with APHIS. That agreement requires the plant protection service to pay, in advance of each shipping season, all costs that APHIS estimates it will incur in providing inspection and treatment monitoring services at the irradiation facility during that shipping season. Those costs include administrative expenses and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by APHIS in performing these services. The agreement will describe the general nature and scope of APHIS services provided at irradiation facilities covered by the agreement, such as whether APHIS inspectors will monitor operations continuously or intermittently, and will generally describe the extent of inspections APHIS will perform on articles prior to and after irradiation. The agreement requires the plant protection service to deposit a certified or cashier's check with APHIS for the amount of those costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement further requires the plant protection service to deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before any more articles irradiated in that country may be imported into the United States. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the plant protection service or held on account until needed, at the option of the plant protection service.

(g) *Packaging.* Fruits and vegetables that are irradiated in accordance with this section must be packaged in cartons in the following manner:

(1) All fruits and vegetables treated with irradiation must be shipped in the same cartons in which they are treated. 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, 250, or 300 gray, depending on the target species of fruit fly or seed weevil).

(3) When designing the facility's dosimetry system and procedures for its operation, the facility operator must address guidance and principles from American Society for Testing and Materials (ASTM) standards[4] or an

[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 ISO/ASTM 51261–2002(E) , ''Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing,'' American Society for Testing and Materials, *Annual Book of ASTM Standards.*

equivalent standard recognized by the Administrator.

(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. (Approved by the Office of Management and Budget under control number 0579–0155)

PART 319—FOREIGN QUARANTINE NOTICES

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

Authority: 7 U.S.C. 166, 450, 7711–7714, 7718, 7731, 7732, and 7751–7754; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

3. In § 319.56–2, a new paragraph (k) is 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 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 is 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 *Sternochetus mangiferae* (Fabricus) or for one or more of the following 11 species of fruit flies: *Anastrepha fraterculus, 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 18th day of October, 2002.

Bobby R. Acord,

Acting Under Secretary, Marketing and Regulatory Programs.

[FR Doc. 02–27027 Filed 10–18–02; 4:38 pm]

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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

Common Crop Insurance Regulations; Forage Seeding Crop Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule; correcting amendment.

SUMMARY: This document contains corrections to the final regulation which was published Wednesday, August 15, 2001 (66 FR 42729–42730). This document pertains to the Forage Seeding Crop Provisions for 2004 and subsequent crop years.

EFFECTIVE DATE: October 23, 2002.

FOR FURTHER INFORMATION CONTACT: Arden Routh, Risk Management Specialist, Product Development Division, Federal Crop Insurance Corporation, United States Department of Agriculture, 6501 Beacon Drive, Kansas City, MO, 64133, telephone (816) 926–7730.

SUPPLEMENTARY INFORMATION:

Background on Need for Correction

The final rule published on August 15, 2001, has a June 30 contract change date and a September 30 cancellation/sales closing date for South Dakota counties with both fall and spring seeded forage. The final planting date for fall seeded forage in these counties