Prefiled Staff Exhibit 44

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 301, 305, 318, and 319

[Docket No. 03–077–2]

Treatments for Fruits and Vegetables

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations by revising the approved doses for irradiation treatment of imported fruits and vegetables. This rule will establish a new minimum generic dose of irradiation for most plant pests of the class *Insecta*, establish a new minimum generic dose for the fruit fly family, reduce the minimum dose of irradiation for some specific fruit fly species, add 10 pests to the list of pests for which irradiation is an approved treatment at less than the generic dose, and provide for the use of irradiation as a treatment for cut flowers and foliage. These actions will allow the use of irradiation to neutralize more pests and to neutralize some pests at lower doses. Furthermore, we are providing for the irradiation of fruits and vegetables moved interstate from Hawaii at the pest-specific irradiation doses that are now approved for imported fruits and vegetables. We are also providing for the use of irradiation to treat fruits and vegetables moved interstate from Puerto Rico and the U.S. Virgin Islands. These actions will allow irradiation to serve as an alternative to other approved treatments for additional commodities moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands. Finally, we are adding irradiation as a treatment for bananas from Hawaii and adding vapor-heat treatment as an optional treatment for sweetpotatoes from Hawaii. These actions will provide an alternative to the currently approved treatments for those commodities while continuing to provide protection against the spread of plant pests from Hawaii into the continental United States.

EFFECTIVE DATE: February 27, 2006.

FOR FURTHER INFORMATION CONTACT: Dr. Inder P.S. Gadh, Senior Risk Manager, Commodity Import Analysis & Operations, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–8758.

SUPPLEMENTARY INFORMATION:

Background

The phytosanitary treatments regulations contained in 7 CFR part 305 set out standards and schedules for treatments required in 7 CFR parts 301, 318, and 319 for fruits, vegetables, and other articles to prevent the introduction or dissemination of plant pests or noxious weeds into or through the United States. Within 7 CFR part 305, the irradiation treatments subpart (§§ 305.31 through 305.34, referred to below as the regulations) sets out standards and minimum doses for irradiation treatment for imported fruits and vegetables and for regulated articles moved interstate from quarantined areas within the United States, along with other requirements for performing irradiation treatments.

On June 10, 2005, we published in the **Federal Register** (70 FR 33857–33873, Docket No. 03–077–1) a proposal to amend the regulations by making several amendments to the irradiation treatment regulations for imported fruits and vegetables, for fruits and vegetables moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands, and for regulated articles moved interstate from areas quarantined for Mexican fruit fly or Mediterranean fruit fly. We also proposed to provide for the use of irradiation treatment for bananas moved interstate from Hawaii and to provide for the use of a vapor heat treatment for sweetpotatoes moved interstate from Hawaii.

On June 20, 2005, the **Federal Register** published a correction (70 FR 35500) to the table in § 305.31(a) of our proposal in which the generic dose for all pests of the phylum *Arthropoda*, excluding adults and pupae of the order *Lepidoptera*, was corrected to read 400 gray.

We solicited comments concerning our proposal for 60 days ending August 9, 2005. We received 13 comments by that date. They were from producers, researchers, representatives of State and foreign agricultural departments, an international industry organization, a public interest organization, and a private citizen. The comments are discussed below by topic.

Issue Outside the Scope of APHIS' Authority

One commenter raised an issue that concerns a matter under the regulatory authority of the Food and Drug Administration (FDA), not the Animal and Plant Health Inspection Service (APHIS). Specifically, the commenter expressed concern that irradiation will make foods unsafe to eat. The commenter stated that irradiation produced 2-alkylcyclobutanones, which she contended is a dangerous residue chemical present in irradiated fruits and vegetables.

The 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 fresh fruits and vegetables. All of the irradiation doses contained in this rule are significantly less than this approved safe dose limit.

Use of Irradiation to Treat Cut Flowers and Foliage

One commenter requested that we also provide for the use of irradiation to treat cut flowers and foliage that are subject to treatment requirements in the regulations.

We agree that cut flowers and foliage that are hosts of pests for which irradiation is an approved treatment can be treated at the pest-specific doses provided in this final rule. Therefore, in this final rule we have amended the phytosanitary treatment regulations as well as the Hawaiian and territorial quarantine regulations to provide for the use of irradiation to treat cut flowers and foliage. Specifically, we have amended paragraph (a) of § 305.31 to provide that irradiation at the pest-specific doses may be used to treat cut flowers and foliage. We have also amended § 305.31 by replacing the words "fruits and vegetables" with the word "article" each time they occur. Sections 305.34, 318.13–4f, and 318.58–4b provide administrative instructions for irradiation treatment of certain fruits

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and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands, respectively. We have amended these sections by replacing the words "fruits and vegetables" with the word "article" each time they occur. Finally, we have amended the cut flowers regulations in § 319.74–2 by adding a new paragraph (d) to indicate that cut flowers may be treated at the pest-specific irradiation doses listed in § 305.31(a). Cut flowers and foliage are also subject to the packaging requirements provided in §§ 305.31 and 305.34 of the regulations.

Irradiation may have negative effects on the quality of cut flowers, and the shipper and facility operator are responsible for determining tolerance of cut flowers to treatment. APHIS assumes no responsibility for any loss or damage that may result in the use of irradiation.

Use of Irradiation To Control Pests

Two commenters objected to the use of irradiation to treat imported fruits and vegetables. One commenter stated that food in the United States has been altered so much that it has become inferior to food in Europe. A second commenter 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. This second commenter added that irradiation has not been shown to be a safe, effective, or viable means to eradicate invasive pests and that the U.S. Department of Agriculture should cease pursuing irradiation as a treatment for plant pests.

We have not made any changes to the rule in response to these comments. 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 can 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. It is true that several technologies under development may also provide effective treatments for various plant pests (*e.g.*, pressure treatments, controlled atmosphere, 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).

One commenter stated that the proposed rule could stimulate the construction of more irradiation facilities, some of which could use radioactive cobalt-60 or cesium-137, which Federal regulations permit. The commenter stated that these facilities will pose serious risks to the communities where they are built.

We are not making any changes in response to this comment. The safety of operations of irradiation facilities is regulated by the Nuclear Regulatory Commission (NRC). NRC ensures that such facilities are built and operated according to Federal regulations. To be licensed, the facility must have been designed with multiple fail-safe measures, and must establish extensive and well-documented safety procedures and worker training. With proper design and operating procedures, commercial irradiation facilities can be operated safely and without posing any significant radiation risk to workers or the public.

Recommended Doses

One commenter presented two studies [1] which demonstrated that Mexican fruit fly (Mexfly) is more radiotolerant than West Indian fruit fly, but noted that we proposed an irradiation dose of 100 Gy for West Indian fruit fly and only 70 Gy for Mexfly. The commenter recommended lowering the dose for West Indian fruit fly to 70 Gy.

We have reviewed the research submitted by the commenter and agree that the dose for West Indian fruit fly (*Anastrepha obliqua*) should be lowered to 70 Gy and have done so in this final rule.

Two commenters stated that it was unnecessary to list green scale in the pest table in § 305.31 because it requires the generic dose (400 Gy). One commenter noted that this implied that 400 Gy was the lowest possible dose that can control green scale. The second commenter added that there has been no large-scale research done on this dose, but that preliminary research at the University of Hawaii suggested 250 Gy would control green scale.

We agree with these commenters and have amended the table in § 305.31(a) by removing the entry for *Coccus viridis*, green scale.

One commenter recommended adding a statement in the final rule that lower irradiation doses might be sufficient for the plant pests being added in this rule in order to encourage more research on minimum irradiation levels.

We are not making any changes as a result of this comment. As stated previously in this document, APHIS is always willing to evaluate research that supports new treatments or changes to existing treatments such as lowering the required doses for irradiation. Petitioners should submit any scientific studies that document the effectiveness of the dose, and APHIS will consider each request as it is presented.

One commenter recommended rounding irradiation doses to the nearest 10 Gy increment because dosimeters can vary by 1 to 2 percent in their accuracy. The commenter added that it is difficult during research to accurately apply doses in less than 10 Gy increments due to variability in the density and consistency of the infested fruit or vegetable.

We are not making any changes in response to this comment. We believe that the measures we have in place to monitor and administer irradiation treatment will ensure that at least the appropriate minimum dose is administered. When applying irradiation treatment, several factors are taken into account, including geometry of the source, the dimensions of the irradiation container, as well as the bulk-density of the load and its distribution. Recording of process parameters and dosimetry is required to ensure that the treatments applied are within the limits established by APHIS. Further, the available data indicate that the doses we proposed are the lowest

[1] Bustos, M.E., Enkerlin, W., Reyes, J., and Toledo, J. 2004. Irradiation of mangoes as a postharvest quarantine treatment for fruit flies (Diptera: Tephritidae). J. Econ. Entomol. 97: 286–292.

Hallman, G.J. and Worley, J.W. 1999. Gamma radiation doses to prevent adult emergence from immatures of Mexican and West Indian fruit flies (Diptera: Tephritidae). J. Econ. Entomol. 92: 967–973.

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effective doses necessary to achieve phytosanitary security; thus, rounding a dose up to the nearest 10 Gy increment would have the effect of requiring more than the minimum dose and would be contrary to our World Trade Organization (WTO) agreements.

Safeguards on Commodity Movement

Two commenters noted that we should put in place safeguards, such as sealed containers, against plant pest spread for untreated commodities that are moved to the mainland United States for treatment. One of the commenters suggested prohibiting movement of untreated commodities with pretreated commodities and adding protocols for transport and containment upon arrival.

Section 305.34 of the regulations sets forth instructions for fruits and vegetables shipped from Hawaii to the mainland United States, including safeguards for untreated commodities being shipped to the mainland United States for treatment. For imported fruits and vegetables, § 305.31, paragraph (g)(1) prohibits packaging irradiated fruits and vegetables with nonirradiated fruits and vegetables and paragraph (g)(2) provides packaging provisions for fruits and vegetables irradiated prior to entering the United States to prevent the entry of fruit flies. However, § 305.31 does not contain packaging provisions for imported fruits and vegetables to be irradiated upon arrival in the United States. Therefore, we are amending § 305.31(g) in this final rule by adding a new paragraph that requires cartons of untreated regulated articles being imported into the United States for treatment to be shipped in shipping containers sealed prior to importation with seals that will visually indicate if the shipping containers have been opened. These provisions we have added regarding imported articles mirror those in § 305.34 for untreated articles moved from Hawaii to the mainland United States for treatment.

Bananas from Hawaii

One commenter stated that the configuration of bananas on the stalk make visual inspections an ineffective detection method. The commenter added that the lethal dose for banana moth should be determined before including this commodity in the regulations.

We have determined that the generic dose of 400 Gy would be sufficient for banana moth larvae; however inspection is necessary for pupae and adults of this pest. Bananas may also undergo irradiation treatment at a dose of 150 Gy for fruit flies, which would require inspection for banana moth and green scale as an additional mitigation measure. We agree with this commenter that the configuration of bananas on the stalk makes visual inspection more difficult. Therefore, we have amended § 318.13–4i, paragraphs (b)(1) and (b)(2), in this final rule to specify that bananas must be removed from the stalk during inspection.

One commenter suggested that we allow green bananas from Hawaii grown under the systems approach to be irradiated at 400 Gy if found to be infested with green scale or to have certain defects that would otherwise trigger rejection upon inspection.

We agree with this commenter and have amended § 318.13–4i in this final rule by revising paragraph (b), introductory text, to state that "Bananas of any cultivar or ripeness that do not meet the conditions of paragraph (a) of this section may also be moved interstate from Hawaii with irradiation in accordance with the following conditions."

Sweetpotatoes

One commenter questioned whether early stages of Kona coffee root-knot nematode could be found by visual inspection.

We have found inspection to be very effective at detecting nematodes of all stages.

One commenter suggested that the regulations should provide that the required probes be placed in the largest roots when applying heat treatment to sweetpotatoes.

We agree that inspectors should locate temperature probes in the largest potatoes when applying heat treatment. Therefore, we have amended § 305.24(k)(1) in this final rule to provide that temperature probes must be placed in the approximate center of the "largest individual sweetpotato roots."

One commenter stated that recent research [2] indicates that sweetpotato weevil, West Indian sweetpotato weevil, and sweetpotato vine borer can all be neutralized with a dose of 150 Gy. The commenter asked that we add West Indian sweetpotato weevil and sweetpotato vine borer with a dose of 150 Gy and that we change the dose for sweetpotato weevil to 150 Gy.

After reviewing the research provided by the commenter, we have amended the table in § 305.31(a) in this final rule by adding entries for West Indian sweetpotato weevil and sweetpotato vine borer and specifying a minimum irradiation dose of 150 Gy for both pests. We have also reduced the minimum irradiation dose for sweetpotato weevil from 165 Gy to 150 Gy.

With these changes, all but one of the pests of concern for sweetpotatoes from Hawaii for which irradiation is an authorized treatment may be treated with a minimum irradiation dose of 150 Gy. The exception is the ginger weevil (*Elytrotreinus subtruncatus*), which requires a minimum irradiation dose of 400 Gy. (The regulations also require inspection for two other pests for which irradiation is not an authorized treatment, *i.e.*, the gray pineapple mealybug [*Dysmicoccus neobrevipes*] and the Kona coffee-root knot nematode [*Meloidogyne konaensis*]). In the proposed rule, we proposed to add a vapor heat treatment option for sweetpotato from Hawaii that included provisions for the sampling, cutting, and inspection of sweetpotatoes for the ginger weevil, and we are adopting those proposed provisions in this final rule (see § 318.13–4d in the regulatory text at the end of this document). To harmonize the irradiation treatment provisions for sweetpotatoes from Hawaii with those new vapor heat provisions, we have amended the regulations in § 305.34 in this final rule to offer two irradiation treatment options: The existing 400 Gy dose or a 150 Gy dose supplemented by sampling, cutting, and inspection for the ginger weevil, with the sampling, cutting, and inspection requirements being the same as those found in the vapor heat provisions in § 318.13–4d. The inspection requirements for the gray pineapple mealybug and the Kona root-knot nematode will continue to apply to sweetpotatoes treated at both the 400 Gy and 150 Gy dose. To effect this change, we have amended § 305.34(b)(7)(i) and (ii) in this final rule to reflect the new inspection requirement for ginger weevil if sweetpotatoes are to be irradiated at 150 Gy; a new footnote in the entry for sweetpotato in the table in paragraph (a)(1) of that section directs the reader to § 305.34(b)(7)(i) and (ii). Because litchi from Hawaii is also subject to additional inspection requirements in § 305.34(b)(7), the entry for litchi in the table has also been annotated with a reference to that footnote.

Pineapples From Hawaii

One commenter asked that we delete the reference to "other than smooth Cayenne" in the entry for pineapples in § 305.34, paragraph (a)(1). The commenter noted that this would allow

[2] Follett, Peter A. Irradiation for postharvest control of Omphisa anastomosalis (Lepidoptera: Pyralidae), Euscepes postfaciatus and Cylas formicarius elegantulus (Coleoptera: Curculionidae) in sweetpotatoes.

all varieties of pineapple to be treated by irradiation for plant pests in accordance with § 305.31(a) and § 305.34(a)(2).

The commenter is correct. We mistakenly included the reference to "other than smooth Cayenne" when in fact, all varieties of pineapple are eligible for irradiation. We have amended the entries for pineapple in § 305.34(a)(1) and § 318.13–4f by removing the words "(other than smooth Cayenne)."

General Comments

In the supplementary information of our proposed rule, we stated that mites are not arthropod plant pests. Two commenters noted that mites are arthropod plant pests and that we should not use the term "arthropod."

We agree with the commenters have amended the last row in the table in § 305.31 by changing the words "phylum *Arthropoda*" to "class *Insecta*."

One commenter suggested that we should explain to inspectors what they can expect to find with properly irradiated commodities (*e.g.*, live fruit flies and perhaps eggs, but no further development from either).

Customs and Border Protection and APHIS inspectors are trained as to what they might specifically find in commodities treated by irradiation and have been inspecting irradiated fruit moved interstate for more than a decade. Therefore, it is unnecessary to include such information in this final rule.

One commenter suggested that we include a provision to prohibit irradiation of low-oxygen-stored produce until research on the effectiveness of irradiation on such produce can be completed. The commenter stated that a recent study showed that four pests showed an increase in radiotolerance when stored in such conditions.

We have no evidence to either support or refute the commenter's concern with the response of pests in low-oxygen-stored produce to irradiation, but agree that irradiation should be only applied to articles that have been stored under certain conditions. Because these conditions may vary based on the specific commodity, pest of concern, or country of origin, we will address specific storage conditions in the operational work plan or the compliance agreement with plant health officials in the areas where commodities are produced, packed, and treated.

One commenter stated that we incorrectly classified the dose ranges for plant pests in the International Plant Protection Convention Guidelines for the Use of Irradiation as a Phytosanitary Measure (ISPM Publication No. 18) as recommended minimum dose ranges. The commenter stated that these doses are only estimates.

We acknowledge that we incorrectly characterized the estimates as recommended minimum doses. That statement appeared in the supplementary information of the proposed rule, however, so there is no need to make any changes to the regulations in this document.

Two commenters stated that research did not demonstrate that all fruit flies of the family *Tephritidae* would be neutralized by a dose of 150 gray.

The commenters are correct in that, technically, all fruit flies of the family *Tephritidae* were not tested, but all of the fruit flies that were tested in this family were neutralized by this dose. Therefore, we consider the results from the fruit flies we tested to be applicable to the entire *Tephritidae* family. However, we agree that it would have been clearer to state that "we consider all fruit flies of the family *Tephritidae* to be neutralized by a dose of 150 gray."

In the supplementary information of the proposed rule, we stated that required irradiation doses were specific to plant pests rather than to the commodities with which they are associated, which reflects the fact that the effectiveness of irradiation treatment is dependent on the dose that is absorbed by the commodity. One commenter considered this statement misleading, noting that it suggests that the radiation is absorbed by the commodity thereby killing the insect. The commenter added that the doses are specific to the pest rather than commodity because the commodity provides limited shielding for the insect from the ionizing radiation.

We agree with this commenter, but because this statement appeared in the supplementary information of the proposed rule, there is no need to make any changes to the regulations in this document.

In the proposed rule, we referred to minimum doses as "pest-specific." One commenter suggested that we use either "pest species-specific" or "individual pest-specific."

We are not making changes in response to this comment. We prefer the general term "pest-specific" which can apply to both individual pests or a pest group (*e.g.*, all fruit flies).

In the proposed rule, we stated that fruit quality problems associated with high irradiation doses prompted us to examine lowering doses. One commenter noted that we made no mention of any financial considerations taken into account.

While economic benefits result from our lowering of irradiation doses, they are not the reason for our doing so. Under WTO agreements, we are obliged to base our regulations on sound science; to ignore research that showed lower irradiation doses to be effective would be contrary to these agreements.

One commenter stated that the proposed rule would open up large parts of the United States to increased risks of infestation. The commenter stated that our reasoning that fruit flies would not survive irradiation treatment or weather conditions in many areas of the United States was faulty. The commenter added that while the rule only applies to 12 species of fruit flies, there are numerous hosts in the United States that would be susceptible to those fruit flies.

We agree that preventing the introduction of exotic fruit flies into the United States is of the utmost importance. According to ARS, 150 Gy will be sufficient to neutralize all fruit flies and that doses lower than 150 gray are sufficient to neutralize certain species of fruit flies. We believe that treatment of fruits, vegetables, cut flowers, and foliage at these doses, when properly administered, will be sufficient to prevent the introduction of fruit flies via commodities treated by irradiation.

Economic Analysis

One commenter suggested that our economic analysis should take note of some advantages to irradiation, such as the fact that fruit that is to be irradiated can be allowed to ripen longer on the tree, resulting in higher-quality fruit.

We have added a paragraph highlighting additional advantages of irradiation over some other treatments to the economic analysis in this final rule.

One commenter stated that it is naive to assume that there are markets for irradiated fruits and vegetables in the United States. The commenter noted that since the FDA legalized the irradiation of fruits and vegetables in 1986, very few types of irradiated produce have been sold in U.S. grocery stores. The commenter also cited the financial troubles of a company that stood to benefit from irradiation as an example of the lack of a market for irradiated fruit in the United States.

The proposed rule and this final rule are concerned with the phytosanitary security of fruits and vegetables and not their marketing. Our regulations offer various treatment options; whether or

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not producers or distributors choose to use irradiation when it is available is up to them.

Miscellaneous

Two commenters pointed out several nonsubstantive editorial errors in the proposed rule. We appreciate the commenters bringing these errors to our attention and wherever appropriate, have made the corrections in this document.

Other Comments

One commenter suggested that in light of the availability of the generic irradiation dose, we reconsider our current pest risk analysis process and require evidence only that the few target pests that could not be treated effectively with irradiation are not present in a particular country or are not pests of concern for a particular commodity, rather than requiring that a list all possible pests be considered in the pest risk analysis.

We agree with this commenter that the availability of the generic irradiation dose may simplify the pest risk analysis process for commodities from countries where pests that can be targeted with the generic dose exist. We expect that a pest list would still have to assembled in most cases, but the risk management aspect of the risk analysis process could be abbreviated if the risks associated with all identified quarantine pests could be addressed through the application of the generic irradiation dose. If quarantine pests that could not be addressed using the generic dose were identified in the pest list, then the risk management analysis could be limited to examining mitigation measures for those pests alone.

The commenter also requested that we reconsider the requirement that every new commodity must be added to the regulations through rulemaking before being eligible for entry into the United States.

While we are unable to make any changes in this document in response to this comment, we are currently developing a proposed rule that would redesign the fruits and vegetables regulations to provide for the evaluation and approval or denial of new import requests in a more expeditious and effective manner.

One commenter asked that we postpone the comment period for the proposed rule because a request submitted by her organization under the Freedom of Information Act (FOIA) regarding another rulemaking related to irradiation had not yet been fulfilled.

We do not believe it is necessary or appropriate to delay this final rule pending the resolution of commenter's FOIA request concerning an entirely separate rulemaking. The APHIS FOIA staff is working to address the request referred to by the commenter.

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.

Executive Order 12866 and Regulatory Flexibility Act

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

This rule makes several amendments to the current provisions for the use of irradiation as a treatment for various plant pests, allows the use of irradiation and inspection as a treatment for bananas moved interstate from Hawaii as an alternative to the systems approach currently described in the regulations, and allows the use of a vapor heat treatment for sweetpotatoes moved interstate from Hawaii as an alternative to fumigation with methyl bromide and irradiation. The potential economic impacts of the changes are discussed below.

Irradiation Treatment for Fruits, Vegetables, Cut Flowers, and Foliage

The regulations in § 305.31 set out standards, minimum doses, and other requirements for performing irradiation treatments on imported fruits, vegetables, cut flowers, and foliage and set out minimum doses necessary to neutralize 11 fruit flies and the mango seed weevil. This rule adds minimum doses for more pests and lowers the minimum doses for others. Specifically, this rule establishes:

- A minimum generic dose of 400 Gy for all plant pests of the class *Insecta* other than pupae and adults of the order Lepidoptera;
- A minimum generic dose of 150 Gy for all fruit flies of the family *Tephritidae*;
- Lower minimum doses for certain fruit flies; and
- New approved minimum doses for 10 plant pests.

This rule also allows irradiation to serve as an alternative to other approved treatments for additional articles moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands. Articles from Hawaii, Puerto Rico, and the U.S. Virgin Islands that are required to be treated by other means for pests listed in § 305.31(a) prior to interstate movement will be allowed to be moved interstate if they are treated with irradiation at the doses listed in § 305.31(a) and in accordance with the other conditions specified in § 305.34.

Section 305.34 has only provided for irradiation treatment of fruits and vegetables from Hawaii; however, we have determined that irradiation treatment can be used effectively for commodities from Puerto Rico and the U.S. Virgin Islands if the safeguards in § 305.34 are implemented. Currently, no irradiation facilities exist in Puerto Rico or the U.S. Virgin Islands, and no requests have been received to approve the construction of such facilities. However, this rule provides for the option of moving the commodities under limited permit to an irradiation facility on the U.S. mainland for treatment prior to entering interstate commerce.

Economic Effects on Small Entities of Changes in Irradiation Treatment Provisions

The Regulatory Flexibility Act requires that agencies specifically consider the economic impact of their regulations on small entities. The Small Business Administration (SBA) has established size criteria using the North American Industry Classification System (NAICS) to determine which economic entities meet the definition of a small firm.

Irradiation facilities affected by this rule will belong to one of the following two NAICS categories: (1) Firms providing irradiation services for the treatment of fruits and vegetables, which would fall within NAICS category 115114, "Postharvest Crop Activities (except Cotton Ginning)"; or (2) firms providing irradiation services for decontamination or sterilization purposes, which would fall within NAICS category 811219, "Medical and surgical equipment repair and maintenance services."

Most treatments of Hawaiian produce are likely to occur at an existing irradiation facility on the island of Hawaii. This facility is used to treat other fruits and vegetables for which irradiation is an approved treatment and can be classified under NAICS category 115114. The SBA criteria classify this facility as a small entity, since its annual sales are less than $6 million.

Another firm on the U.S. mainland operates two facilities in Illinois and one facility in New Jersey. Its primary service is to provide irradiation treatment for the sanitation of medical devices on contract. This firm is classified within NAICS category 811219. However, since it is part of a larger corporation for which annual receipts may exceed $6 million, this

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firm is not classified as a small entity under the SBA criteria. Thus, at least one firm that could be affected by this rule is a small entity.

Irradiation facilities, whether large or small, will benefit from this rule. The range of commodities imported and moved interstate for which irradiation will be an approved treatment will increase. At the same time, dosage levels, and therefore operating costs, will decrease for many commodities. The changes to irradiation doses and provisions allowing the use of pest-specific doses to treat commodities for interstate movement will facilitate the importation of fruits, vegetables, cut flowers, and foliage and their interstate movement from Hawaii, Puerto Rico, and the U.S. Virgin Islands. For certain pests for which irradiation is already an approved treatment, required irradiation dosages will be lowered to the minimum level necessary. In other instances, irradiation will be newly allowed as an alternative phytosanitary treatment.

This rule will result in lower costs and increased flexibility for importers, gains that could be expected to be at least partly realized by U.S. consumers through lower prices, assuming competitive markets. For some commodities, irradiation may also provide quality advantages over other treatment methods in terms of increased shelf life. Irradiation allows fruits and vegetables of higher quality to be imported. Alternative heat, cold, and fumigation treatments can cause unacceptable damage to fruits, vegetables, cut flowers, and foliage. At this time, we are unsure as to the extent of damage the use of irradiation may cause to certain cut flowers and it is entirely the importer's or owner's responsibility to assess which treatment should be used with each variety of cut flowers. Also, these alternative treatments often must be used on fruit harvested before it is fully ripe. Irradiation allows importers to sell riper, more valuable fruit, with less damage. Choice of irradiation as a treatment alternative would rest upon its expected net returns relative to other treatment methods.

Because these changes will have the potential to affect the importation or interstate movement of a wide range of commodities, it is difficult to predict exactly what economic effects these changes will have. However, while affected irradiation firms, large and small, are expected to benefit, we do not expect the impacts to be significant.

Irradiation and Inspection for Bananas Moved Interstate from Hawaii

The regulations in § 318.13–4i have provided that green bananas (*Musa* spp.) of the cultivars "Williams," "Valery," "Grand Nain," and standard dwarf "Brazilian" may be moved interstate from Hawaii under a systems approach. At this time, only green bananas of these specified cultivars have been eligible for interstate movement under those provisions.

We are adding two combinations of irradiation and inspection as treatments for bananas from Hawaii. Specifically, bananas, regardless of cultivar or ripeness, from Hawaii will be eligible for interstate movement if they have been inspected in Hawaii for adults and pupal stages of the banana moth *Opogona sacchari* (Bojen), and have undergone irradiation treatment with a minimum dose of 400 gray at an approved facility. Bananas from Hawaii will also be eligible for interstate movement if they have been inspected in Hawaii for the banana moth and the green scale, *Coccus viridis* (Green), and have undergone irradiation treatment with a minimum dose of 150 gray at an approved facility.

Cost of Irradiation Treatment

The cost of irradiation is estimated at 15 cents per pound.[3] We expect that most bananas moved interstate from Hawaii under this approach will be treated at the existing commercial irradiation facility on the island of Hawaii. However, the treatment could be performed at the irradiation facilities on the mainland United States as well.

Cost of APHIS Inspection

Monitoring of quarantine treatments conducted during standard business hours (weekdays between 8 a.m. and 4:30 p.m.) on the island of Hawaii comes at no cost to the facility. APHIS charges for the monitoring of treatments conducted before 8 a.m. and after 4:30 p.m. and on weekends at a time-and-a-half rate.

Benefits

The combination of irradiation treatment and inspection will offer an alternative to the systems approach for green fruit of the specified four banana cultivars, and will allow fruit of any ripeness or cultivar to be moved interstate from Hawaii. The approach described in this rule can be used to mitigate the pest risk associated with all Hawaiian bananas, regardless of cultivar or ripeness. This will allow banana producers and parties moving bananas interstate greater flexibility in operations, more choices with regard to the types of bananas moved interstate, a greater volume of bananas to ship, and less risk of facing rejections during inspection under the systems approach and Banana Compliance Agreement.

Growers have been reluctant to ship bananas to U.S. mainland markets under the systems approach because § 318.13–4i(c) of the regulations has required that bananas to be moved interstate be inspected by an inspector and found free of the following defects: Prematurely ripe fingers, fused fingers, or exposed flesh (not including fresh cuts made during the packing process). Bananas moved interstate from Hawaii under this systems approach are required to be free of these defects because they are conducive to fruit fly infestation. However, growers are concerned about the risk of having whole shipments of fruit prohibited from interstate movement as a result of a single fault detected when bananas in a random selection of boxes are inspected. No commercial container shipments of bananas have been made to U.S. mainland markets under the regulations in effect prior to this rule. Since the irradiation treatment options provided by this rule are sufficient to neutralize fruit flies and other pests of concern, irradiation will provide the Hawaiian banana industry with an alternative treatment for interstate movement and could open new marketing opportunities.

U.S. consumers will benefit from an increased supply of bananas. Growers in Hawaii believe that the U.S. mainland demand for bananas from Hawaii may be equivalent to (if not higher than) the existing demand for Hawaiian papaya. Hawaiian growers moved approximately 12 million pounds of papayas to U.S. mainland markets in 2003.[4] Demand may be especially high for the apple banana variety, which has a higher sugar content and more aromatic flavor than the standard commercial banana varieties currently available in U.S. mainland markets. Consumers will benefit from the availability of this specialty product.

Hawaii accounts for almost all U.S. banana production.[5] In 2002, there were 677 banana farms in Hawaii,[6] and the value of sales amounted to $ 8.6

[3] Source: Hawaii Department of Agriculture.

[4] Source: Hawaii Department of Agriculture.

[5] The Census of Agriculture (2002) reports minimal acreage in California, Florida, and Texas, which together account for only 131 acres.

[6] National Agricultural Statistics Service, 2002 Census of Agriculture.

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million.[7] Table 1 summarizes production information for bananas and papayas in Hawaii. The utilized production of bananas amounted to 19.5 million pounds in 2002.

TABLE 1.—PRODUCTION STATISTICS FOR BANANAS AND PAPAYAS IN HAWAII (2002)

Item	Bananas	Papayas
Bearing acreage (acres)	1,300	1,720.
Utilized production (1,000 pounds)	19,500	45,900.
Price (per pound)	$0.430	$0.260.
Value of utilized production	$8.385 million	$11.924 million.
Movement to mainland U.S. markets (1,000 pounds)	None	12,000.

Sources: Hawaii Department of Agriculture (movement statistics) and National Agricultural Statistics Service.

The United States imported 7,883 million pounds (3,576 million kg) of fresh bananas in 2003, valued at $959 million.[8] Ecuador, Costa Rica, Guatemala, Colombia, and Honduras accounted for 97 percent of the quantity of imports (table 2). Compared to the 7,883 million pounds of bananas currently imported, Hawaii's total production of 20 million pounds is extremely small, and it is not likely that 100 percent of the State's production will be moved to the mainland United States. Thus, as long as phytosanitary mitigation by means of the approved treatments is maintained, the interstate movement of bananas from Hawaii is unlikely to significantly affect current U.S. trade in fresh bananas.

TABLE 2.—QUANTITY AND VALUE OF FRESH BANANAS IMPORTED INTO THE UNITED STATES FROM THE FIVE MAJOR EXPORTING COUNTRIES (2003)

Country	Quantity (million kg)	Value (million U.S. dollars)
Ecuador	902	237.8
Costa Rica	901	247.5
Guatemala	868	229.1
Colombia	429	117.7
Honduras	388	100.4
Total imports	3,576	959.3

Source: World Trade Atlas (2003).

Economic Effects on Small Entities of Irradiation and Inspection Provisions for Bananas

Most treatments of Hawaiian bananas are likely to occur at the existing irradiation facility on the island of Hawaii, which, as noted previously, is considered a small entity.

Banana farming is classified under NAICS category 111339 as "Other Noncitrus Fruit Farming." The SBA considers entities in this category to be small if their average annual receipts are less than $750,000. The 677 banana farms in Hawaii accounted for annual sales of $8.6 million in total in 2002. Therefore, it is likely that most Hawaiian banana farms will be classified as small entities under the SBA criteria. The treatment monitoring program will be mainly operated by APHIS personnel, and no impact is anticipated on other small entities or government agencies.

Vapor Heat Treatment for Sweetpotatoes Moved Interstate From Hawaii

We are allowing vapor heat treatment, combined with tuber cutting and visual inspection, to be used as a treatment for sweetpotatoes moved interstate from Hawaii. We believe this treatment will be an effective alternative to the methyl bromide and irradiation treatments currently prescribed by the regulations to control pests of concern.

Cost of Vapor Heat Treatment

Hawaii has three packing plants on the Island of Hawaii that provide vapor heat treatment services. No other vapor heat treatment plants are currently in operation elsewhere in the State. Since APHIS has yet to certify a facility for the treatment of sweetpotato by vapor heat, the costs of treating this crop specifically cannot be determined with certainty at this time. However, one of the packinghouses estimated that vapor heat treatment costs could amount to 2 to 3 cents per pound for the required treatment protocol. This estimate considered the costs of labor, electricity, water, and sewer service. APHIS has traditionally certified vapor heat treatment chambers (for example, for papaya) in the "fully loaded configuration." The costs of treating sweetpotato in smaller batch loads still have to be determined. This estimate of treatment cost also does not include a markup for the facility. The markup will be determined by the number of plants providing service and the demand for service.

Cost of APHIS Inspection for Vapor Heat Treatment or Irradiation

Monitoring of quarantine treatments conducted during standard business hours (weekdays between 8 a.m. and 4:30 p.m.) on the island of Hawaii comes at no cost to the facility. APHIS charges for the monitoring of treatments conducted before 8 a.m. and after 4:30 p.m. and on weekends at a time-and-a-half rate.

Comparison of Vapor Heat Treatment, Irradiation, and Methyl Bromide

Vapor heat treatment will provide the Hawaiian sweetpotato industry with an alternative treatment to irradiation or methyl bromide fumigation. If vapor heat treatment can be performed at 2 to 3 cents per pound, it will constitute the most cost-effective treatment, compared to irradiation at 15 cents per pound and fumigation costs ranging from 40.6 cents per pound for 1 pallet to 6.7 cents per pound for 12 pallets (table 3). (These are treatment costs only and do not include the costs of APHIS monitoring or inspection activities or inter-island transportation costs necessary to perform treatments.)

TABLE 3.—ESTIMATED PER-UNIT COST OF VAPOR HEAT TREATMENT, IRRADIATION, AND METHYL BROMIDE FUMIGATION

Treatment	Per unit cost (cents per pound)
Vapor heat treatment	2–3
Irradiation	15

[7] From *http://www.nass.usda.gov/hi/fruit/annban.htm*. Sales of Hawaiian bananas in 2003 were valued at $9.225 million.

[8] World Trade Atlas, 2003.

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TABLE 3.—ESTIMATED PER-UNIT COST OF VAPOR HEAT TREATMENT, IRRADIATION, AND METHYL BROMIDE FUMIGATION—Continued

Treatment	Per unit cost (cents per pound)
Methyl bromide fumigation: [1]	
One pallet	40.6
Two pallets	20.3
Three pallets	13.5
Four pallets	10.1
Five pallets	8.1
Six pallets	6.7
Nine pallets	7.6
Twelve pallets	6.9

[1] One pallet contains 1,500 pounds of sweetpotatoes.

Sources: Packinghouse estimate (vapor heat treatment); Hawaii Department of Agriculture (irradiation and methyl bromide fumigation).

The availability of vapor heat treatment thus provides the Hawaiian sweetpotato industry with an alternative treatment option at a competitive cost. Furthermore, the vapor heat treatment plants in Hawaii will benefit if sweetpotatoes are included in the list of agricultural products to be treated. The availability of vapor heat treatment as an alternative to fumigation might become increasingly important in view of the global phaseout of methyl bromide under the Montreal Protocol. Irradiation may have positive effects on the quality and shelf life of the tubers, and allows flexibility since both small and large product lots can be staged for treatment to meet specific market demands. Vapor heat treatment is not known to offer quality or shelf-life benefits to the product, but some consumers may prefer this option above irradiation, especially in Japan, Canada, and Europe.

Impact on U.S. Sweetpotato Production

Commercial sweetpotato production in Hawaii occurs on the islands of Hawaii, Kauai, Maui, and Oahu. In 2002, there were 59 sweetpotato farms,[9] and the value of sales was $989,000.[10] The utilized production of sweetpotatoes in Hawaii was 1.8 million pounds in 2001 (table 4). The crop is in year-round production in Hawaii.

[9] National Agricultural Statistics Service, 2002 Census of Agriculture.

[10] From *http://www.nass.usda.gov/hi/vegetble/annveg.htm.*

TABLE 4.—PRODUCTION STATISTICS FOR HAWAIIAN SWEETPOTATOES (2001)

Item	Amount
Harvested acres	220
Yield per acre (1,000 pounds)	8.2
Production (1,000 pounds)	1,800
Farm price (cents per pound) [1]	50

[1] The 2001 farm price for sweetpotato was 47.3 cents per pound in Hawaii, Honolulu, and the Kauai Counties, and 60 cents per pound in the Maui County (Hawaiian Department of Agriculture).

Source: Hawaii Agricultural Statistics Service.

In the mainland United States, sweetpotato is grown commercially in Alabama, California, Georgia, Louisiana, Mississippi, New Jersey, North Carolina, South Carolina, Texas, and Virginia. North Carolina, Louisiana, Mississippi, and California account for the major proportion of production area by State (table 5). In total, the United States produced 1,355 million pounds of sweetpotatoes from 93,500 acres in 2003 (table 6). The Hawaiian sweetpotato production of 1.8 million pounds thus comprises a minor proportion of the total production of 1,355 million pounds in the United States.

TABLE 5.—ACRES OF SWEETPOTATOES PLANTED IN THE UNITED STATES (2003)

State	Acres planted
North Carolina	42,000
Louisiana	18,000
Mississippi	14,000
California	10,100
Texas	3,400
Alabama	2,900
Others [1]	3,100
Total	93,500

[1] Including Hawaii.

Source: Economic Research Service, USDA.

TABLE 6.—PRODUCTION AND UTILIZATION STATISTICS FOR SWEETPOTATOES IN THE UNITED STATES (2003) [1]

Item	Amount
Acres planted	93,500
Three-year average yield (cwt/acre)	150
Production (million pounds)	1,355
Imports (million pounds)	17.0
Exports (million pounds)	53.0
Total utilization (million pounds) [2]	1,148.3
Per capita use (pounds)	3.9
Three-year average per capita use (pounds)	4.0
Current dollars ($/cwt)	15.75
Constant 1996 dollars ($/cwt)	13.91

[1] Estimates are for the total United States, and therefore include Hawaii. Forecasted estimates are shown.

[2] Total utilization includes 103 million pounds used for seed and 67.8 million pounds accruing to feed use, shrink, and loss.

Source: Economic Research Service, United States Department of Agriculture. Acres were obtained from Lucier, G. "Sweet potatoes—getting to the root of demand." Economic Research Service, USDA, 2002.

The Hawaiian sweetpotatoes intended for the U.S. mainland markets are of a special purple flesh variety, and they are therefore shipped to the mainland as a specialty product intended for niche markets. U.S. mainland consumers could, therefore, benefit from an increased supply of these specialty sweetpotatoes.

Interstate movement provides Hawaiian growers and shippers with increased marketing opportunities. Sweetpotatoes are in year-round production in Hawaii, but some seasonal variation in volume is expected. Out-shipment to U.S. mainland markets is estimated at 50,000 to 60,000 pounds per week. New plantings of the crop have increased on the island of Hawaii since irradiation was approved as an alternative to methyl bromide fumigation in June 2003. However, plantings are likely to increase each year if the market demand increases for Hawaiian sweetpotatoes regardless of whether the product is treated by methyl bromide fumigation, irradiation, or vapor heat treatment. Nevertheless, even if sweetpotato production increases in Hawaii, the relative volume of production (1.8 million pounds) remains extremely small in comparison to the volume of U.S. mainland sweetpotato production (1.36 billion pounds).

Thus, since Hawaiian production is so small in comparison to U.S. mainland production, and as long as phytosanitary mitigation by the approved treatments is maintained, sweetpotato shipments from Hawaii are unlikely to affect mainland producers. Consumers will benefit from the availability of the purple-fleshed specialty sweetpotato product, and the Hawaiian sweetpotato industry will gain opportunities to expand its mainland U.S. markets.

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Vapor Heat Treatment of Sweetpotatoes Moved Interstate From Hawaii

The availability of vapor heat treatment at a competitive cost could divert some sweetpotatoes moved interstate from Hawaii from the existing irradiation facility in Hawaii to a vapor heat treatment facility. This will affect the existing irradiation facility in Hawaii, which is a small entity. However, it is not known at this time what proportion of Hawaiian sweetpotatoes moved interstate will be treated with vapor heat instead of irradiation.

On the other hand, vapor heat treatment facilities could benefit by the addition of vapor heat as an approved treatment for sweetpotatoes moved interstate from Hawaii. However, since facilities for the vapor heat treatment of Hawaiian sweetpotatoes have not been certified yet, the businesses cannot be conclusively categorized into small or large entities at this time.

Sweetpotato farming is classified under NAICS category 111219, "Other Vegetables (except Potato) and Melon Farming." According to the SBA's criteria, an entity involved in crop production is considered small if it has average annual receipts of less than $750,000. The 59 sweetpotato farms in Hawaii accounted for annual sales of $989,000 in total in 2002. Therefore, it is likely that most of these farms would be considered small entities according to the SBA criteria. The monitoring and inspection program will be mainly operated by APHIS personnel, and no impact is anticipated on other small entities and government agencies.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

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

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

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 0579–0281.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 305

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

7 CFR Part 318

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

7 CFR Part 319

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

■ Accordingly, we are amending 7 CFR parts 301, 305, 318, and 319 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. In § 301.64–10, paragraph (g) introductory text and the OMB control number citation at the end of the section are revised to read as follows:

§ 301.64–10 Treatments.

* * * * *

(g) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of part 305 of this chapter, is approved as a treatment for any fruit listed as a regulated article in § 301.64–2(a).

* * * * *

(Approved by the Office of Management and Budget under control number 0579–0088)

■ 3. In § 301.78–10, paragraph (c) introductory text is revised to read as follows:

§ 301.78–10 Treatments.

* * * * *

(c) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of part 305 of this chapter, is approved as a treatment for any berry, fruit, nut, or vegetable listed as a regulated article in § 301.78–2(a) of this subpart.

* * * * *

PART 305—PHYTOSANITARY TREATMENTS

■ 4. The authority citation for part 305 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 5. Section 305.2 is amended as follows:

■ a. By revising paragraph (h)(1) to read as set forth below.

■ b. In the table in paragraph (h)(2)(ii), under Hawaii, by adding a new entry, in alphabetical order, for "Banana" to read as set forth below.

■ c. In the table in paragraph (h)(2)(ii), under Hawaii, by removing the entry for "Sweet potato" and adding in its place a new entry for "Sweetpotato" to read as set forth below.

§ 305.2 Approved treatments.

* * * * *

(h) *Fruits and vegetables.* (1) Treatment of fruits and vegetables from foreign localities by irradiation in accordance with § 305.31 may be substituted for other approved treatments for any of the pests listed in § 305.31(a). Treatment of fruits and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands by irradiation at the minimum doses listed in § 305.31(a) and in accordance with § 305.34 may be substituted for other approved treatments for any of the pests listed in § 305.31(a).

(2) * * *

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(ii) * * *

Location	Commodity	Pest	Treatment schedule
*	*	*	*
Hawaii			
*	*	*	*
	Banana	*Bactrocera curcurbitae, Bactrocera dorsalis, Ceratitis capitata, Coccus viridis.*	IR.
*	*	*	*
	Sweetpotato	*Euscepes postfasciatus, Omphisa anastomosalis, Elytrotreinus or subtruncatus.*	MB T101–b–3–1 or § 305.24(k) or IR.
*	*	*	*

* * * * *

■ 6. In § 305.24, a new paragraph (k) is added to read as follows:

§ 305.24 Vapor heat treatment schedules.

* * * * *

(k) *Vapor heat treatment for sweetpotatoes moved interstate from Hawaii.* (1) Temperature probes must be placed in the approximate center of the largest individual sweetpotato roots.

(2) The air surrounding the sweetpotato roots must be heated. After the temperature of the air surrounding the sweetpotato roots reaches 87.8 °F (31 °C), its temperature must be incrementally raised from 87.8 °F (31 °C) to 111.2 °F (44 °C) over a period of 240 minutes.

(3) Using saturated water vapor at 118.4 °F (48 °C), the core temperature of the individual sweetpotato roots must be raised to 116.6 °F (47 °C).

(4) After the core temperature of the sweetpotato roots reaches 116.6 °F (47 °C), the core temperature must then be held at 116.6 °F (47 °C) or higher for 190 minutes.

■ 7. Section 305.31 is amended as follows:

■ a. By revising the section heading to read as set forth below.

■ b. By revising paragraph (a), including the table, to read as set forth below.

■ c. By redesignating paragraph (g)(2) as paragraph (g)(3) and adding a new paragraph (g)(2) to read as set forth below.

■ d. In paragraphs (b), (e)(1), (e)(2), (f)(1)(i), (f)(1)(ii), (f)(1)(iii), (g) introductory text, (g)(1), and (n), and in newly redesignated paragraphs (g)(3) introductory text, (g)(3)(i) introductory text, and (g)(3)(ii) introductory text, by removing the words "fruits and vegetables" each time they appear and adding the word "articles" in their place.

■ e. In newly designated paragraph (g)(3)(i)(A), footnote 3, and in paragraph (l), by removing the words "Inspection and" and adding the words "Science and" in their place and by removing the words "1017 Main Campus Drive, suite 2500" and adding the words "1730 Varsity Drive, Suite 400" in their place.

The revisions and additions read as follows:

§ 305.31 Irradiation treatment of imported regulated articles for certain plant pests.

(a) *Approved doses.* Irradiation at the following doses for the specified plant pests, carried out in accordance with the provisions of this section, is approved as a treatment for all regulated articles (i.e., fruits, vegetables, cut flowers, and foliage):

IRRADIATION FOR CERTAIN PLANT PESTS IN IMPORTED REGULATED ARTICLES[1]

Scientific name	Common name	Dose (gray)
Anastrepha ludens	Mexican fruit fly	70
Anastrepha obliqua	West Indian fruit fly	70
Anastrepha serpentina	Sapote fruit fly	100
Anastrepha suspensa	Caribbean fruit fly	70
Bactrocera jarvisi	Jarvis fruit fly	100
Bactrocera tryoni	Queensland fruit fly	100
Brevipalpus chilensis	False red spider mite	300
Conotrachelus nenuphar	Plum curculio	92
Croptophlebia ombrodelta	Litchi fruit moth	250
Cryptophlebia illepida	Koa seedworm	250
Cylas formicarius elegantulus	Sweetpotato weevil	150
Cydia pomonella	Codling moth	200
Euscepes postfasciatus	West Indian sweetpotato weevil	150
Grapholita molesta	Oriental fruit moth	200
Omphisa anastomosalis	Sweetpotato vine borer	150
Rhagoletis pomonella	Apple maggot	60
Sternochetus mangiferae (Fabricus)	Mango seed weevil	300
Fruit flies of the family *Tephritidae* not listed above		150
Plant pests of the class *Insecta* not listed above, except pupae and adults of the order Lepidoptera		400

[1] There is a possibility that some cut flowers could be damaged by such irradiation. See paragraph (n) of this section.

* * * * *

(g) * * *

(2) For all articles to be irradiated upon arrival in the United States, the articles must be packed in cartons that have no openings that will allow the entry of fruit flies and that are sealed with seals that will visually indicate if

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the cartons have been opened. They may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the fruit in the carton.

* * * * *

§ 305.32 [Amended]

■ 8. Section 305.32 is amended as follows:

■ a. In paragraphs (a)(1) and (d), by removing the words "a minimum absorbed ionizing radiation dose of 150 Gray (15 krad)" and adding the words "the approved dose for Mexican fruit fly listed in § 305.31(a)" in their place.

■ b. In paragraph (e)(2), by removing the words "150 Gray (15 krad)" and adding the words "the approved dose for Mexican fruit fly listed in § 305.31(a)" in their place.

■ c. In paragraph (g), by removing the words "Oxford Plant Protection Center, 901 Hillsboro St., Oxford, NC 27565" and adding the words "Center for Plant Health Science and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606" in their place.

§ 305.33 [Amended]

■ 9. Section 305.33 is amended as follows:

■ a. In paragraphs (a)(1) and (d), by removing the words "a minimum absorbed ionizing radiation dose of 225 Gray (22.5 krad)" and adding the words "the approved dose for Mediterranean fruit fly listed in § 305.31(a)" in their place.

■ b. In paragraph (e)(2), by removing the words "225 gray (22.5 krad)" and adding the words "the approved dose for Mediterranean fruit fly listed in § 305.31(a)" in their place.

■ c. In paragraph (g), by removing the words "Oxford Plant Protection Center, 901 Hillsboro St., Oxford, NC 27565" and adding the words "Center for Plant Health Science and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606" in their place.

■ 10. Section 305.34 is amended as follows:

■ a. By revising the section heading to read as set forth below.

■ b. By revising paragraph (a), including the table, to read as set forth below.

■ c. In paragraphs (b) introductory text, (b)(1), (b)(2)(ii), and (b)(4), by adding the words ", Puerto Rico, or the U.S. Virgin Islands" after the word "Hawaii" each time it occurs.

■ d. In paragraphs (b) introductory text, (b)(1), (b)(2)(i), (b)(2)(ii), (b)(4)(i), (b)(4)(ii), (b)(5), (b)(7)(i), (b)(7)(ii), and (e), by removing the words "fruits and vegetables" each time they appear and by adding the word "articles" in their place.

■ e. In paragraph (b)(7)(i), by adding two new sentences after the last sentence to read as set forth below.

■ f. In paragraph (b)(7)(ii), by adding two new sentences after the last sentence to read as set forth below.

■ g. In paragraph (c), by removing the words "1017 Main Campus Drive, suite 2500" and adding the words "1730 Varsity Drive, Suite 400" in their place.

■ h. By revising the OMB control number citation at the end of the section to read as set forth below.

The revisions and additions read as follows:

§ 305.34 Irradiation treatment of certain regulated articles from Hawaii, Puerto Rico, and the U.S. Virgin Islands.

(a) *Approved irradiation treatment.*

(1) *Commodity-specific doses.* Irradiation, carried out in accordance with the provisions of this section, is approved as a treatment for the following fruits and vegetables from Hawaii at the specified dose levels:

IRRADIATION FOR PLANT PESTS IN HAWAIIAN FRUITS AND VEGETABLES

Commodity	Dose (gray)
Abiu	150
Atemoya	150
Bell pepper	150
Carambola	150
Eggplant	150
Litchi[1]	150
Longan	150
Mango	300
Papaya	150
Pineapple	150
Rambutan	150
Sapodilla	150
Italian squash	150
Sweetpotato[1]	400 or 150
Tomato	150

(2) *Pest-specific doses.* Any articles from Puerto Rico or the U.S. Virgin Islands, as well as any articles from Hawaii not listed in paragraph (a)(1) of this section, that are required by part 318 of this chapter to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) may instead be treated with irradiation. Articles treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of this section.

* * * * *

(b) * * *

(7) * * *

(i) * * * In addition, sweetpotato from Hawaii to be treated with irradiation at a dose of 150 Gy must be sampled, cut, and inspected in Hawaii and found to be free of the ginger weevil (*Elytrotreinus subtruncatus*) by an inspector before undergoing irradiation treatment in Hawaii. Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

(ii) * * * In addition, sweetpotato from Hawaii to be treated with irradiation at a dose of 150 Gy must be sampled, cut, and inspected in Hawaii and found to be free of the ginger weevil (*Elytrotreinus subtruncatus*) by an inspector. Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0198 and 0579–0281)

[1] Litchi and sweetpotato are also subject to the additional inspection requirements in paragraph (b)(7) of this section.

PART 318—HAWAIIAN AND TERRITORIAL QUARANTINE NOTICES

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

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

§ 318.13 [Amended]

■ 12. In § 318.13, paragraph (c) is amended by removing the words "leaves in full force and effect § 318.30 which restricts the movement from Hawaii, Puerto Rico, or the Virgin Islands of the United States into or through any other State or certain Territories or Districts of the United States of all varieties of sweetpotatoes (Ipomoea batatas Poir.). It also".

■ 13. Section 318.13–1 is amended as follows:

■ a. In the definition of *compliance agreement,* by removing the words "§ 318.13–3(b), § 318.13–4(b), or § 318.13–4f of this subpart" and adding the words "§ 318.13(b) or § 318.13–4(b) of this subpart or § 305.34 of this chapter" in their place.

■ b. By revising the definition of *inspector* to read as set forth below.

§ 318.13–1 Definitions.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the

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Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

* * * * *

§ 318.13–2 [Amended]

■ 14. In § 318.13–2, in paragraph (b), the list of articles is amended by adding, in alphabetical order, a new entry for "Sweetpotato (Ipomoea batatas Poir.)."

■ 15. Section 318.13–3 is amended as follows:

■ a. By revising paragraph (b)(3) to read as set forth below.

■ b. By adding a new paragraph (b)(4) to read as set forth below.

§ 318.13–3 Conditions of movement.

* * * * *

(b) * * *

(3) Untreated regulated articles from Hawaii may be moved interstate for irradiation treatment on the mainland United States if the provisions of § 305.34 of this chapter are met and if the articles are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c). Untreated bananas from Hawaii may be moved interstate for irradiation treatment on the mainland United States if the provisions of § 318.13–4i(b) are met and if the bananas are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c). The limited permit will be issued only if the inspector examines the shipment and determines that the shipment has been prepared in compliance with the provisions of this subpart.

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

* * * * *

§ 318.13–4b [Amended]

■ 16. Section 318.13–4b is amended as follows:

■ a. By adding the words "or vegetables" after the word "fruits" in the following places:

i. The section heading.

ii. Paragraph (a).

iii. Paragraph (b), in the paragraph heading and the first sentence.

iv. Paragraph (c).

v. Paragraph (e).

vi. Paragraph (f).

■ b. In paragraph (b), by removing the words "fruit flies" and adding the words "plant pests" in their place.

■ c. In paragraph (b), by adding the word "sweetpotatoes," after the word "rambutan,".

■ 17. A new § 318.13–4d is added to read as follows:

§ 318.13–4d Vapor heat treatment of sweetpotatoes from Hawaii.

(a) Vapor heat treatment, carried out in accordance with the provisions of this section, is approved as a treatment for sweetpotato from Hawaii.

(b) Sweetpotatoes may be moved interstate from Hawaii in accordance with this section only if the following conditions are met: [2]

(1) The sweetpotatoes must be treated in accordance with the vapor heat treatment schedule specified in § 305.24.

(2) The sweetpotatoes must be sampled, cut, and inspected and found to be free of the ginger weevil (*Elytrotreinus subtruncatus*). Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

(3) The sweetpotatoes must be inspected and found to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*) and the Kona coffee-root knot nematode (*Meloidogyne konaensis*).

(4)(i) Sweetpotatoes that are treated in Hawaii must be packaged in the following manner:

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

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

(*1*) With polyethylene sheet wrap;

(*2*) With net wrapping; or

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

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

(ii) Cartons of untreated sweetpotatoes that are moving to the mainland United States for treatment must be shipped in shipping containers sealed prior to interstate movement with seals that will visually indicate if the shipping containers have been opened.

(5)(i) *Certification on basis of treatment.* A certificate shall be issued by an inspector for the movement of sweetpotatoes from Hawaii that have been treated and handled in Hawaii in accordance with this section. To be certified for interstate movement under this section, sweetpotato from Hawaii must be sampled, cut, and inspected by an inspector and found by an inspector to be free of the ginger weevil (*Elytrotreinus subtruncatus*) and inspected and found by an inspector to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*), and the Kona coffee-root knot nematode (*Meloidogyne konaensis*) before undergoing vapor heat treatment in Hawaii.

(ii) *Limited permit.* A limited permit shall be issued by an inspector for the interstate movement of untreated sweetpotato from Hawaii for treatment on the mainland United States in accordance with this section. To be eligible for a limited permit under this section, untreated sweetpotato from Hawaii must be sampled, cut, and inspected in Hawaii by an inspector and found by an inspector to be free of the ginger weevil (*Elytrotreinus subtruncatus*) and inspected and found by an inspector to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*), and the Kona coffee-root knot nematode (*Meloidogyne konaensis*).

(Approved by the Office of Management and Budget under control number 0579–0281)

■ 18. Section 318.13–4f is revised to read as follows:

§ 318.13–4f Irradiation treatment of certain regulated articles from Hawaii.

Irradiation, carried out in accordance with the provisions in § 305.34 of this chapter, is approved as a treatment for the following fruits and vegetables: Abiu, atemoya, bell pepper, carambola, eggplant, litchi, longan, mango, papaya, pineapple, rambutan, sapodilla, Italian squash, sweetpotato, and tomato. Any

[2] Sweetpotatoes may also be moved interstate from Hawaii in accordance with § 305.34 of this chapter or after fumigation with methyl bromide according to treatment schedule T–101–b–3–1, as provided for in § 305.6(a) of this chapter.

[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, Center for Plant Health Science and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606.

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other commodities that are required by this subpart to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Commodities treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.

■ 19. Section 318.13–4i is amended as follows:

■ a. By revising the section heading to read as set forth below.

■ b. By redesignating paragraphs (a), (b), (c), and (d) as paragraphs (a)(1), (a)(2), (a)(3), and (a)(4), respectively, and by designating the introductory text of the section as paragraph (a), introductory text.

■ c. By adding a new paragraph (b) to read as set forth below.

§ 318.13–4i Conditions governing the movement of bananas from Hawaii.

* * * * *

(b) Bananas of any cultivar or ripeness that do not meet the conditions of paragraph (a) of this section may also be moved interstate from Hawaii in accordance with the following conditions:

(1) The bananas are irradiated at the minimum dose listed in § 305.31(a) of this chapter and in accordance with the other requirements in § 305.34 of this chapter for the Mediterranean fruit fly (*Ceratitis capitata*), the melon fruit fly (*Bactrocera curcurbitae*), the Oriental fruit fly (*Bactrocera dorsalis*), and the green scale (*Coccus viridis*) and are inspected, after removal from the stalk, in Hawaii and found to be free of the banana moth (*Opogona sacchari* (Bojen)) by an inspector before or after undergoing irradiation treatment; or

(2) The bananas are irradiated at the minimum dose listed in §A305.31(a) of this chapter and in accordance with the other requirements in § 305.34 of this chapter for the Mediterranean fruit fly (*Ceratitis capitata*), the melon fruit fly (*Bactrocera curcurbitae*), and the Oriental fruit fly (*Bactrocera dorsalis*) and are inspected, after removal from the stalk, in Hawaii and found to be free of the green scale (*Coccus viridis*) and the banana moth (*Opogona sacchari* (Bojen)) before or after undergoing irradiation treatment.

(3)(i) A certificate shall be issued by an inspector for the movement of bananas from Hawaii that have been treated and inspected in Hawaii in accordance with this paragraph § 318.13–4i(b). To be certified for interstate movement under this paragraph, bananas from Hawaii must be treated, inspected, and, if necessary, culled in accordance with the requirements of this paragraph prior to interstate movement from Hawaii.

(ii) A limited permit shall be issued by an inspector for the interstate movement of untreated bananas from Hawaii for treatment on the mainland United States in accordance with this section. To be eligible for a limited permit under this paragraph § 318.13–4i(b), bananas from Hawaii must be inspected in accordance with the requirements of this paragraph prior to interstate movement from Hawaii.

§ 318.13–5 [Amended]

■ 20. In § 318.13–5, footnote 6 is redesignated as footnote 4.

§ 318.13–12 [Amended]

■ 21. In § 318.13–12, footnotes 7 and 8. are redesignated as footnotes 5 and 6, respectively.

§ 318.13–17 [Amended]

■ 22. In § 318.13–17, footnotes 9 and 10 are redesignated as footnotes 7 and 8, respectively.

Subpart—Sweetpotatoes [Removed]

■ 23. Subpart—Sweetpotatoes, consisting of §§ 318.30 and 318.30a, is removed.

§ 318.58 [Amended]

■ 24. In § 318.58, paragraph (d) is amended by removing the words "leaves in full force and effect § 318.30 which restricts the movement from Hawaii, Puerto Rico, or the Virgin Islands of the United States into or through any other State or certain Territories or Districts of the United States of all varieties of sweetpotatoes (Ipomoea batatas Poir.). It also".

■ 25. In § 318.58–1, the definition of *inspector* is revised to read as follows:

§ 318.58–1 Definitions.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

* * * * *

§ 318.58–2 [Amended]

■ 26. In § 318.58–2, in paragraph (b)(2), the list of articles is amended by adding, in alphabetical order, a new entry for "Sweetpotato (Ipomoea batatas Poir.)."

■ 27. A new section § 318.58–4b is added to read as follows:

§ 318.58–4b Irradiation treatment of regulated articles from Puerto Rico and the U.S. Virgin Islands.

Any regulated articles from Puerto Rico or the U.S. Virgin Islands that are required by this subpart to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Commodities treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.

■ 28. A new section § 318.58–4c is added to read as follows.

§ 318.58–4c Movement of sweetpotatoes from Puerto Rico to certain ports.

Sweetpotatoes from Puerto Rico may be moved interstate to Atlantic Coast ports north of and including Baltimore, MD, if the following conditions are met:

(a) The sweetpotatoes must be certified by an inspector of the Commonwealth of Puerto Rico as having been grown under the following conditions:

(1) Fields in which the sweetpotatoes have been grown must have been given a preplanting treatment with an approved soil insecticide.

(2) Before planting in such treated fields, the sweetpotato draws and vine cuttings must have been dipped in an approved insecticidal solution.

(3) During the growing season an approved insecticide must have been applied to the vines at prescribed intervals.

(b) An inspector of the Commonwealth of Puerto Rico must certify that the sweetpotatoes have been washed.

(c) The sweetpotatoes must be graded by inspectors of the Commonwealth of Puerto Rico in accordance with Puerto Rican standards which do not provide a tolerance for insect infestation or evidence of insect injury and found by such inspectors to comply with such standards prior to movement from Puerto Rico.

(d) The sweetpotatoes must be inspected by an inspector and found to be free of the sweetpotato scarabee (*Euscepes postfasciatus* Fairm.).

PART 319—FOREIGN QUARANTINE NOTICES

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

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

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§ 319.56–2 [Amended]

■ 30. In § 319.56–2, paragraph (k) is amended by removing the words "11 species of fruit flies and one species of seed weevil" and adding the words "plant pests" in their place.

■ 31. Section 319.74–2 is amended as follows by redesignating paragraph (d) as paragraph (e) and by adding a new paragraph (d) to read as follows:

§ 319.74–2 Conditions governing the entry of cut flowers.

* * * * *

(d) *Irradiation.* Cut flowers and foliage that are required under this part to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Commodities treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34 of this chapter. There is a possibility that some cut flowers could be damaged by such irradiation.

* * * * *

Done in Washington, DC, this 20th day of January 2006.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 06–746 Filed 1–26–06; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 52

RIN 3150–AH56

AP1000 Design Certification

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) is amending its regulations to certify the AP1000 standard plant design. This action is necessary so that applicants or licensees intending to construct and operate an AP1000 design may do so by referencing this regulation [AP1000 design certification rule (DCR)]. The applicant for certification of the AP1000 design was Westinghouse Electric Company, LLC (Westinghouse).

DATES: *Effective Date:* The effective date of this rule is February 27, 2006. The incorporation by reference of certain material specified in this regulation is approved by the Director of the Office of the Federal Register as of February 27, 2006.

FOR FURTHER INFORMATION CONTACT: Lauren Quinones-Navarro or Jerry N. Wilson, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone (301) 415–2007 or (301) 415–3145; e-mail: *lnq@nrc.gov* or *jnw@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background.
II. Comment Analysis
  A. Design Control Document
  B. Design Certification Rule
III. Section-by-Section Analysis
  A. Introduction (Section I)
  B. Definitions (Section II)
  C. Scope and Contents (Section III)
  D. Additional Requirements and Restrictions (Section IV)
  E. Applicable Regulations (Section V)
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  I. Inspections, Tests, Analyses, and Acceptance Criteria (Section IX)
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IV. Availability of Documents
V. Voluntary Consensus Standards
VI. Finding of No Significant Environmental Impact: Availability
VII. Paperwork Reduction Act Statement
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IX. Regulatory Flexibility Certification
X. Backfit Analysis
XI. Congressional Review Act

I. Background

Subpart B of 10 CFR part 52 sets forth the process for obtaining standard design certifications. On March 28, 2002 (67 FR 20845; April 26, 2002), Westinghouse tendered its application for certification of the AP1000 standard plant design with the NRC. Westinghouse submitted this application in accordance with subpart B and appendix O of 10 CFR part 52. The NRC formally accepted the application as a docketed application for design certification (Docket No. 52–006) on June 25, 2002 (67 FR 43690; June 28, 2002). The pre-application information submitted before the NRC formally accepted the application can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) under Docket Number PROJ0711 (Project No. 711).

The NRC staff issued a final safety evaluation report (FSER) for the AP1000 design in September 2004 (NUREG–1793). The FSER provides the bases for issuance of a final design approval (FDA) under appendix O to part 52, which is a prerequisite to a design certification. The FDA for the AP1000 design was issued on September 13, 2004, and published in the **Federal Register** on September 17, 2004 (69 FR 56101). A proposed rule to certify the AP1000 was published on April 18, 2005 (70 FR 20062).

Subsequently, Westinghouse submitted editorial and minor technical changes and clarifications to the inspections, tests, analyses, and acceptance criteria (ITAAC) in revision 15 to the design control document (DCD). The NRC staff evaluated these changes in a supplement to the FSER (NUREG–1793, Supplement No. 1). Supplement No. 1 is being made available to the public as part of this rulemaking. The FSER and Supplement No. 1 provide the bases for the Commission's approval of the AP1000 standard plant design. An FDA, which incorporates the changes to the DCD, will be issued to supersede the current FDA after issuance of this final design certification rule.

II. Comment Analysis

The period for submitting comments on the proposed DCR, AP1000 DCD, or draft environmental assessment (EA) expired on July 5, 2005. The NRC received three letters from two private citizens and one letter from the Nuclear Energy Institute (NEI). The comments addressed three categories of information: Environmental Assessment (EA), Design Control Document, and Design Certification Rule. The responses to the comments on the EA are discussed in section 7.0 of the EA (ML053630176). Responses to the comments in the second and third categories are discussed below.

A. Design Control Document (DCD)

Comment summary. There is an over-reliance on passive systems in the AP1000.

Response. The NRC disagrees with this comment. The NRC required tests of the new passive safety systems to demonstrate that they will perform as predicted in the safety analysis (see Chapter 21 of the AP1000 FSER). The NRC also required higher availability for certain active backup systems to compensate for any remaining uncertainties in the performance of the passive safety systems (see Chapter 22 of the AP1000 FSER). As a result of these reviews, the NRC concluded that the use of passive safety systems in the AP1000 design is acceptable.

Comment Summary. The AP1000 is an unnecessary and unsafe variation on AP600.

Response. The NRC disagrees with the comment. The NRC has determined that the AP1000 design can be built and operated safely (see AP1000 FSER). The

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