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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 305 and 319

[Docket No. APHIS-2009-0100]

RIN 0579-AD35

Irradiation Treatment; Location of Facilities in the Southern United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the phytosanitary treatment regulations to provide generic criteria for new irradiation treatment facilities in the Southern States of the United States. This action will allow irradiation facilities to be located anywhere in these States, subject to approval, rather than only in the currently approved locations. We are also amending the regulations to allow for the irradiation treatment of certain imported fruit from India and Thailand upon arrival in the United States. This action will facilitate the importation of fruit requiring irradiation treatment while continuing to provide protection against the introduction of pests of concern into the United States.

EFFECTIVE DATE: [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Inder P. S. Gadh, Senior Risk Manager—Treatments, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; (301) 851-2018.

SUPPLEMENTARY INFORMATION:

Background

The phytosanitary treatment regulations contained in 7 CFR part 305 (referred to below as the regulations) set out the general requirements for performing treatments and certifying or approving treatment facilities for fruits, vegetables, and other articles to prevent the introduction or dissemination of plant pests or noxious weeds into or through the United States. The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) administers these regulations.

The regulations in § 305.9 set out irradiation treatment requirements for imported regulated articles; regulated articles moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands; and regulated articles moved interstate from areas quarantined for certain pests of concern. In § 305.9, paragraph (a)(1) allows irradiation treatment facilities to be located in any State of the United States, except for the Southern States of Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, and Virginia. The regulations do allow irradiation facilities to be located at the maritime ports of Gulfport, MS, and Wilmington, NC, and the airport of Atlanta, GA.

The regulations in § 305.9 also allow for irradiation treatment of articles either prior to or after arrival in the United States, provided an APHIS-approved facility is available. The regulations in parts 318 and 319 allow the importation of certain fruits from India (mangoes), Mexico (guavas), Pakistan (mangoes), Thailand (litchis, longans, mangoes, mangosteens, pineapples, and rambutans), and Vietnam (dragon fruits), and the interstate movement of several fruits and vegetables from Hawaii, after they have received irradiation treatment. While the

regulations in parts 318 and 319 provide that fruits and vegetables moving from Mexico, Pakistan, Vietnam, and Hawaii may receive irradiation at either the point of origin or upon arrival in the mainland United States, the regulations in part 319 require fruit from India and Thailand to be treated prior to arrival in the United States.

On September 29, 2011, we published in the Federal Register a proposal¹ (76 FR 60390-60395, Docket No. APHIS-2009-0100) to amend § 305.9 by establishing generic phytosanitary criteria to replace the current criteria for irradiation facilities at the maritime ports of Gulfport, MS, and Wilmington, NC, and the airport of Atlanta, GA, and to apply the proposed generic criteria to any new irradiation treatment facilities in the Southern States of the United States. Under these criteria, in conjunction with the current criteria for irradiation facilities not located in the Southern States, we proposed to allow new irradiation facilities to be established in all the Southern States for the treatment of regulated articles that are imported, moved interstate from Hawaii or U.S. territories, or moved interstate from areas quarantined for certain pests of concern. We also proposed to amend § 319.56-46 to allow for irradiation treatment of mangoes from India either prior to or after arrival in the United States and § 319.56-47 to allow for irradiation treatment of tropical fruits from Thailand either prior to or after arrival in the United States.

We solicited comments concerning our proposal for 60 days ending November 28, 2011. We received seven comments by that date. One comment consisted of 3,529 identical or nearly identical letters. The comments were from an advocacy group, a State department of agriculture, and private citizens. Two commenters expressed support for the proposed rule. The remaining comments are discussed below by topic.

¹ To view the proposed rule, supporting and related documents, and the comments received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0100>.

Some commenters stated that irradiation is an inappropriate way to deal with the risk of plant pests in imported foods. One commenter generally opposed the use of irradiation as a phytosanitary measure. One commenter opposed the rule as no irradiation facilities have been built in the currently approved locations in Southern States.

Under the Plant Protection Act (7 U.S.C. 7701 et seq.), regulated articles may be subject to remedial measures necessary to prevent the spread of plant pests. APHIS has determined that irradiation is an effective form of treatment against certain plant pests, and the regulations in 7 CFR part 305 provide for irradiation as a phytosanitary treatment for commodities or articles that require treatment prior to interstate movement or importation. Before approving irradiation as a treatment alternative for a specific pest, APHIS performs an evaluation to determine its effectiveness. As irradiation has been determined to be effective, there is no reason to deny importers the use of this treatment option.

Several commenters expressed concern about importing commodities into the United States prior to irradiation treatment, with one commenter indicating that Florida is a high-risk area for fruit flies and other invasive exotic pests. Another commenter stated that allowing irradiation facilities in Southern States would make it easier for pests to infest key agricultural States and expressed concern about the cost of containing and eradicating exotic pests. One commenter questioned why pest mitigation is not occurring prior to export and did not understand why the United States would perform this task for exporters.

As we indicated in the proposed rule, the regulations in § 305.9 allow for irradiation treatment of articles either prior to or after arrival in the United States, provided that an APHIS-approved facility is available. Articles may be treated in the United States instead of the exporting country for several reasons, including when the exporting country lacks the resources,

technical expertise, or infrastructure to treat articles prior to export. The regulations require safeguards that have successfully prevented the introduction or dissemination of plant pests into or within the United States via the importation or interstate movement of irradiated articles since 1996, when irradiation was first used as a phytosanitary treatment. Based on our experience, we are confident that exporting countries have the ability to comply with all APHIS requirements and commodities from exporting countries can be safely treated in the United States.

APHIS recognizes that the Southern States have conditions favorable for the establishment of exotic fruit flies, and that is why we proposed additional safeguards for irradiation facilities in these States that go beyond the current requirements that apply to all irradiation facilities. These safeguards include the requirements that untreated articles may not be removed from their packaging prior to treatment under any circumstances, that refrigerated or air-conditioned conveyances must be used to transport regulated articles to the treatment facility, and that facilities have contingency plans for safely destroying or disposing of regulated articles if the facility was unable to properly treat a shipment. To help prevent establishment of pests in the unlikely event that they escape despite the required precautions, we will require trapping and other pest monitoring activities within 4 square miles of the facility to help prevent establishment of any escaped pests of concern. Those activities will be paid for by the facility. In addition, while APHIS monitors the treatment, the costs of treatment are the responsibility of the exporter or the importer, not APHIS.

APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from a port of entry or points of origin in the United States. We believe that the mitigations included in this final rule have proven effective in mitigating the risk associated with the importation of commodities into the United

States, and thus will provide protection against the introduction or dissemination of pests of concern into the United States. In the environmental assessment (EA) that we prepared for the proposed rule, we evaluated the potential environmental effects from allowing untreated commodities to be transported into the Southern United States. In the EA, we determined that the mitigation measures included in this final rule are adequate to manage pest risks associated with amending the irradiation regulations and are expected to provide an effective level of phytosanitary protection.

Several commenters were concerned that the increased importation of commodities into the United States would have adverse economic effects on domestic producers. One commenter expressed concern that irradiation facilities are expensive and would increase the cost of food.

This rule does not authorize the importation of any additional fruits or vegetables, so it will not in and of itself lead to the increased importation of commodities. Any new imports would have to be authorized through our existing provisions in 7 CFR part 319. While the availability of additional treatment capacity in new areas might spur businesses to explore new or additional imports of articles, the PPA authorizes APHIS to consider plant pest risks when determining whether to allow new articles to be imported, rather than potential economic competition.

With respect to the costs of irradiation increasing the costs of food, the final rule does not add irradiation requirements for any commodity and therefore will not add any costs. We also note that in most cases a variety of phytosanitary treatments for a particular article will be available, so importers and marketers will choose the treatment option that makes the most sense to them from an economic and competitive standpoint. Products are unlikely to be imported unless their importation is economically feasible.

Many comments raised several issues that concern matters under the regulatory authority of other Federal 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 commenter suggested that irradiation facilities are unsafe and that workers may be exposed to dangerous levels of radiation. Many other commenters stated that USDA should not put consumers, U.S. farmers, and communities at risk by expanding the use of irradiation.

The Nuclear Regulatory Commission, the Occupational Safety and Health Administration, and the U.S. 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. In § 305.9(b) of the final rule, we are requiring other agencies that have regulatory oversight and requirements regarding irradiation facilities to concur in writing with the establishment of the facility prior to APHIS approval. In our EA, we evaluated the potential environmental effects from irradiation facilities and found that, provided required safety standards and control procedures are adhered to, no impacts to the human environment are expected.

Many commenters expressed concern that irradiation will make foods unsafe to eat. Commenters also stated that irradiation would reduce the nutritional value of fruits and vegetables, particularly through vitamin depletion. One commenter stated that “many of the exporting countries will not have regulatory frameworks comparable to what U.S. producers are subjected to and irradiation will be used as a panacea to address those shortcomings.” One

commenter stated that irradiation can be a cover-up for poor food handling practices and could also mask the effects of spoilage.

The Food and Drug Administration (FDA) has primary regulatory responsibility for ensuring that approved irradiation doses do not render foods unsafe to eat. In our EA, we discuss the safety of food that has been irradiated, finding that irradiation does not harm the nutritional value of food, nor does it make the food unsafe to eat or adversely affect the balance between microbial spoilage organisms and pathogenic organisms. Regulation of these matters, however, is outside the scope of the current rulemaking and outside the statutory authority of APHIS. We do note for the record the following information from the August 2000 report by the U.S. General Accounting Office (now known as the U.S. Government Accountability 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.

One commenter stated that the FDA has not been able to keep up with the volume of imports to ensure that they are safe for human consumption.

This matter is outside the scope of the current rulemaking and outside the statutory authority of APHIS. However, on this point we do note that the Food Safety Modernization Act was enacted on January 4, 2011, to enable FDA to better protect public health by strengthening the food safety system.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Order 12866 and Regulatory Flexibility Act

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

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

The final rule will benefit U.S. entities by clearly and transparently presenting the criteria that will govern the approval of additional irradiation facilities in the Southern United States, thereby facilitating their establishment. APHIS has not identified any costs associated with establishing the generic criteria for irradiation facility approval described in the rule.

Beyond helping to make the approval of future irradiation facilities in the Southern United States an efficient process, we do not anticipate that the criteria set forth in this rule will result in economic impacts on U.S. entities, large or small.

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

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.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that providing generic criteria for new irradiation treatment facilities in the Southern States of the United States will 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 (NEPA), as amended (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).

The environmental assessment and finding of no significant impact may be viewed on the Regulations.gov Web site.² Copies of the environmental assessment and finding of no significant impact are also 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- 0383.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

² Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0100>. The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

List of Subjects

7 CFR Part 305

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

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 305 and 319 as follows:

PART 305—PHYTOSANITARY TREATMENTS

1. 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.

2. Section 305.9 is amended as follows:

- a. By revising paragraph (a)(1) to read as set forth below.
- b. In paragraph (b), by adding a sentence after the first sentence to read as set forth below.
- c. By adding a sentence after the paragraph (c) introductory text heading to read as set forth below.
- d. In paragraph (e) introductory text, by adding a sentence after the second sentence to read as set forth below.
- e. In paragraph (e)(1) introductory text, by adding a new first sentence after the paragraph heading to read as set forth below.

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

§ 305.9 Irradiation treatment requirements.

* * * * *

(a) * * *

(1) Where certified irradiation facilities are available, an approved irradiation treatment may be conducted for any imported regulated article either prior to shipment to the United States or in the United States. For any regulated article moved interstate from Hawaii or U.S. territories, irradiation treatment may be conducted either prior to movement to the mainland United States or in the mainland United States. Irradiation facilities may be located in any State on the mainland United States. For irradiation facilities located in the States of Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, and Virginia, the following additional conditions must be met:

(i) Prospective facility operators must submit a detailed layout of the facility site and its location to APHIS. APHIS will evaluate plant health risks based on the proposed location and layout of the facility site. APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from port of entry or points of origin in the United States.

(ii) The government of the State in which the facility is to be located must concur in writing with the establishment of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not

concur with the proposed facility location, APHIS and the State will agree on a strategy to resolve the pest risk concerns prior to APHIS approval.

(iii) Untreated articles may not be removed from their packaging prior to treatment under any circumstances.

(iv) The facility must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles if the facility is unable to properly treat a shipment.

(v) The facility may only treat articles approved by APHIS for treatment at the facility. Approved articles will be listed in the compliance agreement required in paragraph (c)(1)(i) of this section.

(vi) Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility.

(vii) Regulated articles must be conveyed to the facility in a refrigerated (via motorized refrigeration equipment or other methods including ice or insulation) or air-conditioned conveyance at a temperature that minimizes the mobility of the pests of concern for the article.

(viii) The facility must maintain and provide APHIS with an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility. Proximity of host material to the facility will necessitate trapping or other pest monitoring activities to help prevent establishment of any escaped pests of concern, as approved by APHIS; these activities will be listed in the compliance agreement required in paragraph (c)(1)(i) of this section. The treatment facility must have a pest management plan within the facility.

(ix) The facility must comply with any additional requirements that APHIS may require to prevent the escape of plant pests during transport to and from the irradiation facility itself, for a particular facility based on local conditions, and for any other risk factors of concern. These activities will be listed in the compliance agreement required in paragraph (c)(1)(i) of this section.

* * * * *

(b) * * * Other agencies that have regulatory oversight and requirements must concur in writing with the establishment of the facility prior to APHIS approval. * * *

(c) * * * Compliance agreements for facilities located in States listed in paragraph (a)(1) of this section may also contain additional provisions as described in paragraphs (a)(1)(i) through (a)(1)(ix) of this section. * * *

* * * * *

(e) * * * Facilities must be located within the local commuting area for APHIS employees for inspection purposes.

(1) * * * Facilities shall be located within an area over which the U.S. Department of Homeland Security is assigned authority to accept entries of merchandise, to collect duties, and to enforce the provisions of the customs and navigation laws in force. * * *

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(Approved by the Office of Management and Budget under control numbers 0579-0155, 0579-0215, and 0579-0198, 0579-0383)

PART 319—FOREIGN QUARANTINE NOTICES

3. 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.

§ 319.56-46 [Amended]

4. Section § 319.56-46 is amended as follows:

a. In paragraph (a), by removing the words “in India”.

b. In paragraph (e) introductory text, by removing the words “certifying that the fruit received the required irradiation treatment. The phytosanitary certificate must also bear” and adding the word “with” in their place.

§ 319.56-47 [Amended]

5. Section 319.56-47 is amended as follows:

a. In paragraph (b), by removing the second sentence.

b. In paragraph (c)(1), by removing the words “that the litchi were treated with irradiation as described in paragraph (b) of this section and”.

c. In paragraph (c)(2), by removing the words “with an additional declaration stating that the longan, mango, mangosteen, pineapple, or rambutan were treated with irradiation as described in paragraph (b) of this section”.

Done in Washington, DC, this 16th day of July 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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