

Proposed Rules

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 318

[Docket No. 01-042-1]

Interstate Movement of Gardenia From Hawaii

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Hawaiian fruits and vegetables regulations to provide for the movement of cut blooms of gardenia from Hawaii. We have determined that specific growing and inspection protocols or treatment with irradiation can effectively mitigate the plant pest risks associated with gardenia grown in Hawaii. This action would provide for the interstate movement of gardenia from Hawaii while continuing to prevent the spread of plant pests within the United States.

DATES: We will consider all comments we receive that are postmarked, delivered, or e-mailed by July 15, 2002.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 01-042-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 01-042-1. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 01-042-1" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building,

14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT:

Donna L. West, Import Specialist, Phytosanitary Issues Management, Import and Interstate Services, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1231; (301) 734-6766.

SUPPLEMENTARY INFORMATION:

Background

The regulations in "Subpart—Hawaiian Fruits and Vegetables" (7 CFR 318.13 through 318.13-17, referred to below as the regulations) govern, among other things, the interstate movement of fruits, vegetables, and other products, including cut flowers, from Hawaii. Regulation is necessary to prevent the spread of plant pests that exist in Hawaii.

The regulations in § 318.13-3(b)(1) currently provide that cut flowers (except cut blooms of gardenia, mauna loa, and jade vine, and leis thereof) may be moved interstate under certain conditions and if accompanied by a limited permit. The movement of cut blooms of gardenia is currently prohibited due to gardenia's status as a host of green scale (*Coccus viridus*), also known as green coffee scale.

The green scale feeds along the main vein of the leaf and near the tips of green shoots. Damage due to the feeding of an individual scale is small. However, when large populations are present, yellowing, defoliation, reduction in fruit set, and loss in plant vigor occur. In addition, green scale excrete honeydew. This sweet and watery excretion is fed on by bees, wasps, ants, and other insects. The honeydew serves as a medium on which a sooty fungus grows, called sooty mold. Sooty mold blackens the leaf and decreases photosynthesis.

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In this document, we are proposing to amend the regulations to provide for the interstate movement of gardenia from Hawaii. Cut blooms of gardenia from Hawaii would be eligible for movement to other parts of the United States if they were treated with irradiation in Hawaii or grown in accordance with certain prescribed conditions. Each of these options is explained below.

Irradiation Protocol for Cut Blooms of Gardenia

Section 318.13-4f provides instructions for the irradiation treatment of fruits and vegetables from Hawaii. Research conducted by the University of Hawaii and reviewed by the U.S. Department of Agriculture's (USDA's) Agricultural Research Service has demonstrated that the irradiation treatment described in that section is an effective treatment for green scale on gardenias, so we are proposing to add cut blooms of gardenia to the list in 318.13-4f(a) of regulated articles for which irradiation is an approved treatment. We would also make some minor changes throughout the section, such as replacing references to "fruits and vegetables" with references to "regulated articles," to ensure that the section's provisions apply to gardenias. A description of the provisions of § 318.13-4f as they currently stand is set forth below. Our specific proposed changes are discussed after that description.

Currently, paragraph (b) of § 318.13-4f provides that:

1. Irradiation treatment must be carried out at an approved facility only in Hawaii or in non-fruit-fly-supporting areas of the mainland United States (i.e., States other than Alabama, Arizona, California, Florida, Georgia, Kentucky, Louisiana, Mississippi, Nevada, New Mexico, North Carolina, South Carolina, Tennessee, Texas, or Virginia). With one limited exception, prior to treatment, the fruits and vegetables cannot move into or through these non-fruit-fly-supporting States;

2. The irradiation treatment facility and treatment protocol must be approved by the Animal and Plant Health Inspection Service (APHIS);

3. In order to be approved, a facility must be capable of administering a minimum absorbed ionizing radiation dose of 250 Gray (25 krad), be constructed so as to provide physically separate locations for treated and

untreated fruits and vegetables, complete a compliance agreement with APHIS, and be certified by Plant Protection and Quarantine, APHIS, for initial use and annually for subsequent use;

4. Irradiation treatment must be monitored by an inspector, who may be either an APHIS employee or a designated State plant regulatory official;

5. If treated in Hawaii, the fruits and vegetables must be packaged in cartons that have no openings that will allow the entry of fruit flies. The cartons must be sealed with seals that will visually indicate if the cartons have been opened. Then, the pallet-load of cartons must be wrapped, before leaving the irradiation facility, in one of the following ways: (1) With polyethylene sheet wrap; (2) with net wrapping; or (3) with strapping so that each carton on an outside row of the pallet-load is constrained by a metal or plastic strap. In addition, pallet-loads must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment;

6. If moving to the mainland for treatment, the untreated fruits and vegetables must be shipped in shipping containers sealed prior to interstate movement with seals that will visually indicate if the shipping containers have been opened;

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

8. Dosimetry systems in the irradiation facility must map, control, and record the absorbed dose;

9. The absorbed dose must be measured by a dosimeter that can accurately measure an absorbed dose of 250 Gray (25 krad);

10. The number and placement of dosimeters must be in accordance with American Society for Testing and Materials standards;

11. An inspector will issue a certificate for the interstate movement of fruits and vegetables treated and handled in Hawaii in accordance with the regulations at § 318.13–4f. An inspector will issue a limited permit for the interstate movement of untreated fruits and vegetables from Hawaii for irradiation treatment on the mainland United States; and

12. The irradiation facility must keep records or invoices for each treated lot for a period that exceeds the shelf life of the irradiated food product by 1 year and must make those records available to an inspector for inspection.

Paragraphs (c) and (d) of § 318.37–4f set forth procedures for applying for

approval and inspection of a treatment facility, and procedures for denial and withdrawal of approval.

Paragraph (e) of § 318.13–4f further provides that the USDA and its inspectors are not responsible for any loss or damage resulting from any treatment prescribed or supervised.

The one substantive change we would make to the provisions described above is with regard to the location of treatment. As described in item 1 above, the irradiation treatment may be carried out in Hawaii or in a non-fruit-fly-supporting area of the mainland United States. Because green scale can survive in those non-fruit-fly supporting areas, we would require that cut blooms of gardenia be treated only in Hawaii. To put this restriction in place, we would make two changes to the regulations. First, we would amend the first sentence of § 318.13–4f(b)(1) to read, “The irradiation treatment must be carried out at an approved facility in Hawaii or, if authorized by a limited permit issued under paragraph (b)(7)(ii) of this section, on the mainland United States.” Second, we would amend the provisions in § 318.13–4f(b)(7)(ii) regarding limited permits to state that cut blooms of gardenia may be treated only in Hawaii and are not eligible for a limited permit for movement to the mainland United States for treatment. A limited permit is already required under § 318.13–4f(b)(7)(ii) for the movement of untreated fruits and vegetables to the mainland for treatment, so these proposed change would have no effect on the current requirements governing the movement of fruits and vegetables.

As noted previously, it would be necessary to change the references to “fruits and vegetables” that appear in several places to “regulated articles” to include cut blooms of gardenias within the scope of the regulations. In addition, our proposed addition of provisions for the interstate movement of cut blooms of gardenias would make several other changes necessary. Specifically, we would:

- Change the title of the subpart from “Subpart Hawaiian Fruits and Vegetables” to “Subpart—Hawaiian Fruits, Vegetables, and Flowers.”

- Add an entry for cut blooms of gardenias to the list in § 318.13–2(b) of regulated articles that are eligible for interstate movement from Hawaii.

- Modify the prohibition in § 318.13–3(b)(1) on the movement of cut blooms of gardenia to limit that prohibition to cut blooms that have not been treated with irradiation or grown under the conditions described in this document.

- Amend § 318.13–4f(e) to include green scale along with the Trifly

complex (i.e., Mediterranean fruit fly, melon fruit fly, and Oriental fruit fly) as a pest against which irradiation is approved as a treatment to assure quarantine security.

Systems Approach

As an alternative to the irradiation treatment described above, cut blooms of gardenia would also be eligible for interstate movement from Hawaii if the gardenias were grown and shipped under the following conditions:

1. The grower's production area would have to be inspected annually by an inspector and found free of green scale. If green scale is found during an inspection, a 2-month ban would be placed on the interstate movement of cut blooms of gardenia from that production area unless the grower chose to have the blooms treated with irradiation in accordance with § 318.13–4f. Near the end of the 2-month period, an inspector would reinspect the grower's production area to determine whether green scale is present. If reinspection determines that the production area is free of green scale, shipping could resume. If reinspection determines that the production area still has green scale, another 2-month ban on shipping would be placed on the movement of gardenia from that production area. The grower, at this point, would again have the option of treating the blooms with irradiation, rather than waiting 2 months for reinspection.

2. The gardenia production area would have to be surrounded by a buffer area extending 20 feet from the edge of the production area. Within the buffer area, the growing of gardenias and other green scale host plants would be prohibited. The following 18 green scale hosts would be specified as prohibited in the buffer area: Ixora, ginger (*Alpinia purpurata*), plumeria, coffee, rambutan, lichee, guava, citrus, anthurium, avocado, banana, cocoa, macadamia, celery, *Pluto indicia* (a weed introduced into Hawaii), mango, orchids, and annona.

3. An inspector would have to visually inspect the cut blooms of gardenias in each shipment prior to their interstate movement from Hawaii. If the inspector does not detect green scale in the shipment, the inspector would issue a certificate in accordance with § 318.13–4(a), which would allow the shipment to move interstate without further restrictions. If the inspector finds green scale in a shipment, that shipment would have to be treated with irradiation in accordance with § 318.13–4f to be eligible for interstate movement from Hawaii.

These proposed growing and shipping conditions would provide gardenia producers with an opportunity to move pest-free cut blooms of gardenia interstate without treatment while at the same time making irradiation treatment available as an option should green scale be detected in their production areas or on cut blooms offered for interstate movement.

In addition to the changes discussed above, we are also making several nonsubstantive changes to correct editorial errors in the regulations.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The 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 this document, we are proposing to amend the regulations to provide for the movement of cut blooms of gardenia from Hawaii. We have determined that specific growing and inspection protocols or treatment with irradiation can effectively mitigate the plant pest risks associated with gardenia grown in Hawaii. This action would provide for the interstate movement of gardenias from Hawaii while continuing to prevent the spread of plant pests within the United States.

Under this proposed rule, gardenia growers in Hawaii who wish to move cut blooms of gardenia interstate from Hawaii would be able to do so if the gardenias were produced in a growing area determined by APHIS to be free of green scale and the cut blooms were inspected prior to interstate movement. Alternatively, cut blooms of gardenia could be moved interstate from Hawaii if the blooms were treated with irradiation prior to movement.

Gardenia Producers

According to the USDA's Pacific Basin Agricultural Research Center in Hawaii, the total planted area of gardenias in Hawaii is 26.6 acres. Of the 26.6 acres of gardenias, only 3.6 acres belong to commercial farms: 2 acres in Kona, on the island of Hawaii; 1.1 acres in the Manoa Valley (Oahu), and 0.5 acres in Waipahu (Oahu). The remaining 23 acres of planted gardenias in Hawaii are owned by approximately 100 growers, each having an average of 20 to 25 bushes or about 10,000 square feet of production area. These gardenias are grown in "backyard" type production conditions.

The largest commercial gardenia production area in Hawaii consists of 2

acres of planted gardenia bushes that produce about 69,200 flowers per year, with annual gross receipts from sales of just under \$13,000. While sales figures are not available for the two smaller commercial producers, we presume that their annual sales are less than those of the largest producer.

According to Small Business Administration (SBA) size standards, an entity involved in floriculture production (NAICS code 111422) is considered a small entity if it has annual sales of less than \$750,000. Under this definition, all commercial gardenia growers in Hawaii would be considered small entities.

Irradiation Facility

The proposed irradiation treatment of gardenias would take place prior to their shipment to the mainland United States at an irradiation facility on the island of Hawaii. This facility began its commercial operation in August 2000 and is currently approved by APHIS for the irradiation of fruits and vegetables under § 318.13–4f of the regulations.

The irradiation facility can be classified under NAICS code 115114, "Postharvest Crop Activities (except Cotton Ginning)." According to SBA standards, an entity in that classification is considered a small entity if its annual sales are less than \$6 million. Applying this definition, the facility would be considered a small entity.

Impact on Small Entities

Under the Regulatory Flexibility Act, agencies are required to specifically consider the economic effects of their rules on small entities. The entities most likely to be affected by this proposed rule are the commercial producers of gardenias and the irradiation treatment facility discussed previously in this analysis; the producers and treatment facility are all considered to be small entities.

We expect that commercial gardenia producers would benefit from the ability to move their products interstate to markets in the continental United States while incurring the costs associated with establishing and maintaining a green-scale-free growing area and/or treating the cut blooms with irradiation. While we cannot estimate the amount of additional sales that might be enjoyed by commercial gardenia producers as a result of this proposed rule, we do not expect that amount would be substantial, given the limited scale of commercial gardenia production in Hawaii. The costs associated with the proposed production area requirements are likely to be negligible and limited to the maintenance of a 20-foot host-plant-

free buffer zone around the production area, as the required inspections will be provided free of charge. The costs for irradiating fruit currently ranges from \$0.22 to \$0.33; how those costs would translate to the cost of irradiating cut blooms of gardenias is unknown, given the differing weight-volume ratios of fruit and cut flowers. In order for the treatment to be cost effective, treatment costs would have to be only a small percentage of the producer price for the cut blooms, which, according to the Pacific Basin Agricultural Research Center, range from \$3.50 per 10 units for heads to \$9.80 per 10 units for fancy extra-long (12 inches and above) stems.

We also expect that the irradiation facility used for treating cut blooms of gardenias would benefit from this proposed rule. However, in the absence of data regarding the number of gardenia producers that would use the facility, the volume of business those producers would bring, and the prices that the facility would charge for irradiating cut blooms, we cannot estimate the size of those benefits. Nonetheless, we expect that the amount of additional revenue that could result from this proposed rule would be small, given the limited scale of commercial gardenia production in Hawaii.

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

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget

(OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 01-042-1. Please send a copy of your comments to: (1) Docket No. 01-042-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

We are proposing to amend the Hawaiian fruits and vegetables regulations to provide for the movement of cut blooms of gardenia from Hawaii. We have determined that specific growing and inspection protocols or treatment with irradiation can effectively mitigate the plant pest risks associated with gardenia grown in Hawaii. This action would provide for the interstate movement of gardenia from Hawaii while continuing to prevent the spread of plant pests within the United States.

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

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

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

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

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

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.425 hours per response.

Respondents: Gardenia producers, irradiation facility personnel, and State plant regulatory officials.

Estimated annual number of respondents: 13.

Estimated annual number of responses per respondent: 6,1538.

Estimated annual number of responses: 80.

Estimated total annual burden on respondents: 34 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

List of Subjects in 7 CFR part 318

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

Accordingly, we propose to amend 7 CFR part 318 as follows:

PART 318—HAWAIIAN AND TERRITORIAL QUARANTINE NOTICES

1. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 7711, 7712, 7714, 7731, 7754, and 7756; 7 CFR 2.22, 2.80, and 371.3.

Subpart Hawaiian Fruits, Vegetables, and Flowers

2. The heading for the subpart would be revised to read as set forth above.

§ 318.13-1 [Amended]

3. In § 318.13-1, in the definition of *fruits and vegetables*, the word "mellons" would be corrected to read "melons".

§ 318.13-2 [Amended]

4. In § 318.13-2, paragraph (b) would be amended as follows:

a. In the introductory text, by removing the words "fruits and vegetables" and adding the word "articles" in their place.

b. In the list of regulated articles, by adding, in alphabetical order, an entry for "Gardenia (cut blooms)".

c. At the end of the section, in the sentence following the list, by removing the words "and vegetables" and adding the words ", vegetables, or other products" in their place and by removing the words "fruits or vegetables" and adding the words "articles" in their place.

§ 318.13-3 [Amended]

5. In § 318.13-3, paragraph (b)(1) would be amended by removing the words "gardenia, mauna loa," and adding the words "mauna loa" in their place and by adding the words ", and except any cut blooms of gardenia not treated in accordance with § 318.13-4f

or grown in accordance with § 318.13-4j" after the word "thereof".

§ 318.13-4 [Amended]

6. Section 318.13-4 would be amended as follows:

a. In paragraph (a), by removing the words "Fruits and vegetables" and adding "Regulated articles" in their place.

b. In paragraph (c)(2), by removing the words "fruits and vegetables" and adding the words "fruits, vegetables, or other products" in their place.

7. Section 318.13-4f would be amended as follows:

a. By revising the section heading.

b. In paragraph (a), by removing the words "fruits and vegetables" and adding the words "regulated articles" in their place and by adding the words "gardenia (cut blooms)," after the word "carambola,".

c. In paragraph (b), the introductory text, by removing the words "Fruits and vegetables" and adding the words "Regulated articles" in their place.

d. In paragraph (b)(1) by revising the first sentence.

e. In paragraph (b)(2)(i) by removing the words "fruits and vegetables" and adding the word "articles" in their place.

f. In paragraph (b)(2)(ii), in the first sentence, by removing the words "fruits and vegetables" both times they occur and adding the word "articles" in their place and, in the second sentence, by removing the word "six" and adding the numeral "6" in its place.

g. In paragraph (b)(3) by removing the words "inspectional visits to" and adding the words "inspections of" in their place.

h. In paragraph (b)(5), by removing the word "fruits and vegetables" and adding the word "articles" in their place.

i. In paragraph (b)(7)(i), by removing the words "fruits and vegetables" and adding the words "regulated articles" in their place.

j. In paragraph (b)(7)(ii), by adding a new sentence at the end of the paragraph to read as follows.

k. In paragraph (e), by adding the words "and green scale" after the words "Trifly complex" and by removing the words "fruits and vegetables" and adding the word "articles" in their place.

The revisions and addition read as follows:

§ 318.13-4f Administrative instructions prescribing methods for irradiation treatment of certain regulated articles from Hawaii.

* * * * *

(b) * * *

(1) * * * The irradiation treatment must be carried out at an approved facility in Hawaii or, if authorized by a limited permit issued under paragraph (b)(7)(ii) of this section, on the mainland United States. * * *

* * * * *

(7) * * *

(ii) * * * Cut blooms of gardenia may be treated only in Hawaii and are not eligible for a limited permit for movement to the mainland United States for treatment.

* * * * *

8. A new 318.13-4j would be added to read as follows:

\$ 318.13-4j Administrative instructions governing the interstate movement of cut blooms of gardenia from Hawaii.

Cut blooms of gardenia may be moved interstate from Hawaii if treated with irradiation in accordance with § 318.13-4f of this subpart or if grown and inspected in accordance with the provisions of this section.

(a) The grower's production area must be inspected annually by an inspector and found free of green scale. If green scale is found during an inspection, a 2-month ban will be placed on the interstate movement of cut blooms of gardenia from that production area unless the grower elects to treat the blooms with irradiation in accordance with § 318.13-4f. Near the end of the 2 months, an inspector will reinspect the grower's production area to determine whether green scale is present. If reinspection determines that the production area is free of green scale, shipping may resume. If reinspection determines that green scale is still present in the production area, another 2-month ban on shipping will be placed on the interstate movement of gardenia from that production area unless the grower again elects to treat the blooms with irradiation in accordance with § 318.13-4f. Absent irradiation, each ban will be followed by reinspection in the manner specified, and the production area must be found free of green scale prior to interstate movement.

(b) The grower must establish a buffer area surrounding gardenia production areas. The buffer area must extend 20 feet from the edge of the production area. Within the buffer area, the growing of gardenias and the following green scale host plants is prohibited: Ixora, ginger (*Alpinia purpurata*), plumeria, coffee, rambutan, litchi, guava, citrus, anthurium, avocado, banana, cocoa, macadamia, celery, *Pluto indicia* (a weed introduced into Hawaii), mango, orchids, and annona.

(c) An inspector must visually inspect the cut blooms of gardenias in each shipment prior to interstate movement from Hawaii to the mainland United States. If the inspector does not detect green scale in the shipment, the inspector would issue a certificate for the shipment in accordance with § 318.13-4(a). If the inspector finds green scale in a shipment, that shipment must be treated with irradiation in accordance with § 318.13-4f to be eligible for interstate movement from Hawaii.

Done in Washington, DC, this 9th day of May 2002.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02-12135 Filed 5-14-02; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 112 and 113

[Docket No. 93-129-1]

Viruses, Serums, Toxins, and Analogous Products; Equine Influenza Vaccine, Killed Virus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations concerning Standard Requirements for veterinary biologics by adding a Standard Requirement for Equine Influenza Vaccine, Killed Virus. This proposed rule would require that such vaccines be shown to protect vaccinees for at least 60 days based on a vaccination-challenge study conducted in horses. In addition, we would establish a serum hemagglutination inhibition test in guinea pigs as the serial release potency test for the vaccine; establish procedures for adding and removing strains of virus based on evidence of changes in the antigenic character of the equine influenza viruses in current circulation; and add labeling requirements to the regulations. The effect of these proposed changes would be to standardize purity, safety, potency, and efficacy requirements for equine influenza vaccine to ensure that such products will provide a minimum level of protection to vaccinated horses.

DATES: We will consider all comments we receive that are postmarked, delivered, or e-mailed by July 15, 2002.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 93-129-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 93-129-1. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 93-129-1" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support, Center for Veterinary Biologics, Licensing and Policy Development, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20737-1231; (301) 734-8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 113 (referred to below as the regulations) prescribe Standard Requirements for the preparation and testing of veterinary biological products. A Standard Requirement consists of test methods, procedures, and criteria that define the standards of purity, safety, potency, and efficacy for a given type of veterinary biological product. When a Standard Requirement for a product type does not exist, test methods, procedures, and criteria for evaluating the purity, safety, potency, and efficacy are provided in an Outline of Production for the product filed with the Animal and Plant Health Inspection Service (APHIS). Once uniform standards for a type of product are established, they are codified in the regulations as a Standard Requirement.