

Dated: August 27, 2004.

Anthony J. Principi,
Secretary of Veterans Affairs.

Environmental Protection Agency

40 CFR Part 26

RIN 2080-AA10

List of Subjects in 40 CFR Part 26

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 26, as set forth at the end of this document.

The authority for part 26 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: May 16, 2005.

Stephen L. Johnson,
Acting Administrator.

Department of Health and Human Services

45 CFR Part 46

RIN 0940-AA10

List of Subjects in 45 CFR Part 46

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 46, as set forth at the end of this document.

The authority for part 46 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289; 42 U.S.C. 300v-1(b).

Dated: June 15, 2005.

Ann Agnew,
Executive Secretary to the Department.

National Science Foundation

45 CFR Part 690

RIN 3145-AA42

List of Subjects in 45 CFR Part 690

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the National Science Foundation amends 45 CFR part 690, as set forth at the end of this document.

The authority for part 690 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: June 30, 2004.

Lawrence Rudolph,
General Counsel.

Department of Transportation

49 CFR Part 11

RIN 2105-XX97

List of Subjects in 49 CFR Part 11

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Transportation amends 49 CFR part 11, as set forth at the end of this document.

The authority for part 11 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: September 18, 2004.

Norman Y. Mineta,
Secretary of Transportation.

Editorial Note: This document was received at the Office of the Federal Register on June 17, 2005.

■ Accordingly, the Federal Policy for the Protection of Human Subjects is amended as follows:

§ ____ .101 [Amended]

■ 1. Amend § ____ .101 as follows:

■ a. In paragraph (i), remove the words “Office for Protection from Research Risks, Department of Health and Human Services (HHS),” and add, in their place, “Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office,”.

■ b. In footnote 1 at the end of paragraph (i), remove the words “prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C.” and add, in their place, “prisoners, subpart C.”.

§ ____ .103 [Amended]

■ 2. Amend § ____ .103 as follows:

■ a. In paragraph (a), in the second and last sentences, remove the words, “Office for Protection from Research Risks, HHS” and add, in their place, “Office for Human Research Protections, HHS, or any successor office”.

■ b. In paragraph (b)(3), remove the words “Office for Protection from Research Risks, HHS” and add, in their place, “Office for Human Research Protections, HHS, or any successor office”.

■ c. Revise the parenthetical at the end of the section to read as follows:

§ ____ .103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

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(Approved by the Office of Management and Budget under Control Number 0990-0260.)

■ 3. Revise the parenthetical at the end of § ____ .109 to read as follows:
§ ____ .109 IRB review of research.

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(Approved by the Office of Management and Budget under Control Number 0990-0260.)

§ ____ .110 [Amended]

■ 4. In paragraph (a), remove the words “Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.” and add, in their place, “Office for Human Research Protections, HHS, or any successor office.”.

■ 5. Revise the parenthetical at the end of § ____ .113 to read as follows:

§ ____ .113 Suspension or termination of IRB approval of research.

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(Approved by the Office of Management and Budget under Control Number 0990-0260.)

■ 6. Revise the parenthetical at the end of § ____ .115 to read as follows:

§ ____ .115 IRB records.

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(Approved by the Office of Management and Budget under Control Number 0990-0260.)

■ 7. Revise the parenthetical at the end of § ____ .116 to read as follows:

§ ____ .116 General requirements for informed consent.

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(Approved by the Office of Management and Budget under Control Number 0990-0260.)

■ 8. Revise the parenthetical at the end of § ____ .117 to read as follows:

§ ____ .117 Documentation of informed consent.

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(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[FR Doc. 05-12394 Filed 6-22-05; 8:45 am]

BILLING CODE 4150-36-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 05-005-2]

Citrus Canker; Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the citrus canker regulations by updating the list of areas in the State of Florida quarantined because of citrus canker. The interim rule expanded one established quarantined area, added several new quarantine areas, and removed a portion of one quarantined area. These actions were necessary to prevent the spread of citrus canker into noninfested areas of the United States and to relieve restrictions that were no longer warranted.

DATES: The interim rule became effective on February 25, 2005.

FOR FURTHER INFORMATION CONTACT: Ms. Lynn Evans-Goldner, Assistant Staff Officer, Pest Detection and Management Programs, PPQ, APHIS, 4700 River Road Unit 137, Riverdale, MD 20737-1236, (301) 734-7228.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule effective and published in the **Federal Register** on February 25, 2005 (70 FR 9207-9210, Docket No. 05-005-1), we amended the regulations in "Subpart—Citrus Canker" (7 CFR 301.75 through 301.75-16) by updating the list in § 301.75-4 of areas in the State of Florida quarantined because of citrus canker. Specifically, to reflect the detection of citrus canker in an area adjacent to, but outside of, one current quarantined area in Florida, as well as in three additional areas, we expanded the boundaries of one existing quarantined area in DeSoto County and added several new areas in Charlotte, Collier, and Hendry Counties to the list of quarantined areas. We also removed portions of Manatee County from the list of quarantined areas because regular surveys showed them to have been free of citrus canker for at least 2 years. These actions were necessary to prevent the spread of citrus canker into noninfested areas of the United States and to relieve restrictions that were no longer warranted.

Comments on the interim rule were required to be received on or before April 26, 2005. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866, Executive Orders 12372 and 12988, and the Paperwork Reduction Act. Further, for this action, the Office of

Management and Budget has waived its review under Executive Order 12866.

Regulatory Flexibility Act

This rule affirms an interim rule that amended the regulations by updating the list of areas in the State of Florida quarantined because of citrus canker. The interim rule added three new quarantined areas based on the disease's discovery in the Burnt Store and the Farabee Grade quarantined areas in Charlotte County and the Collier quarantined area in Collier and Hendry Counties. The interim rule also expanded the area covered by the DeSoto B quarantined area in DeSoto County. The interim rule imposed certain restrictions on the interstate movement of regulated articles from and through these quarantined areas. The interim rule also removed the quarantined area in Manatee County from the list of areas quarantined for citrus canker. Therefore, the interim rule was necessary to prevent the spread of citrus canker into noninfested areas of the United States and to remove unnecessary restrictions. The following analysis addresses the economic effect of the interim rule on small entities, as required by the Regulatory Flexibility Act.

Citrus canker is a bacterial disease causing lesions on the leaves, stems and fruit of citrus trees. The lesions allow the bacterium to reproduce in moisture-enriched environments. The bacteria that cause citrus canker can seep from the lesions and spread to other trees and, ultimately, other groves. The main contributing factors in the spread of citrus canker are contact by grove workers and equipment and wind-driven rain. Citrus varieties have varying degrees of susceptibility to the disease. For example, grapefruit varieties are more vulnerable to the spread of citrus canker than some varieties of oranges, such as Valencia oranges.

Costs incurred because of citrus canker derive both from the damage caused by the disease as well as from private, State, and Federal funds expended on control measures. Among the reported costs are public expenditures for eradication and for compensation of affected growers. Approximately \$600 million has been devoted to eradicating citrus canker. Compensation payments by APHIS to affected growers over the past 4 fiscal years have totaled \$105.2 million. The first round of payments for fiscal years 2000 and 2001 totaled \$76.8 million. Payments for fiscal years 2003 and 2004 were \$11.8 million and \$16.6 million, respectively. The interim rule expanded

the list of quarantined areas in an effort to thwart the spread of citrus canker to other citrus-producing areas of the United States. The objective is to control the spread of citrus canker and thereby minimize its costs to private and public entities, as described above.

The small business size standard identified by the Small Business Association (SBA), based upon the North American Industry Classification System (NAICS) codes 111310 (orange groves) and 111320 (other citrus not oranges), is \$750,000 or less in annual receipts. The interim rule affected a total of eight growers and six harvesters. One grower and four harvesters are located in the Collier quarantined area. In the Burnt Store quarantined area, the interim rule affected two growers and two harvesters; however, they are not harvesting this year. In the DeSoto B quarantine expansion, five growers are included in the quarantine expansion; three of these growers, however, were already affected by the same or other quarantine zones. No packinghouses or other affected businesses are located within this expanded quarantined area. Although the size of these affected entities is unknown, it is reasonable to assume that most are small in size according to the SBA's standards.

Based on the experiences of citrus growers and harvesters in areas previously placed under quarantine, APHIS does not expect compliance with these restrictions on the movement of regulated fruit from the newly quarantined areas to have a significant economic effect on small entities in the three newly quarantined areas. An alternative to this rule would be to leave the regulations unchanged. However, failing to include these new areas in the regulations would be an unsatisfactory decision. As citrus canker can be transmitted by human means and via wind-driven rain, choosing to leave the regulations unchanged would likely lead to the spread of the disease from these areas to other citrus-producing areas.

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.

List of Subjects in 7 CFR Part 301

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

PART 301—DOMESTIC QUARANTINE NOTICES

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 301 and that was published at 70 FR 9207–9210 on February 25, 2005.

Done in Washington, DC, this 17th day of June 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–12436 Filed 6–22–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****7 CFR Parts 301 and 305**

[Docket No. 04–092–2]

Phytophthora Ramorum; Vacuum Heat Treatment for Bay Leaves

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the phytosanitary treatments regulations to allow leaves of the California bay laurel (*Umbellularia californica*) to be treated with vacuum heat before being moved interstate from any area quarantined because of *Phytophthora ramorum*. This action will provide an alternative to the hot water dip that had been the only approved treatment for the greenery of host plants, which include California bay laurel leaves, but that ruined the suitability of the leaves for use as a dried spice.

DATES: Effective June 23, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. James Writer, Assistant *P. ramorum* Program Manager, Invasive Species and Pest Management, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1231; (301) 734–7121.

SUPPLEMENTARY INFORMATION:**Background**

The regulations in “Subpart-Phytophthora Ramorum” (7 CFR 301.92 through 301.92–11, referred to below as the regulations) list 10 counties in California and a portion of Curry County in Oregon as quarantined areas due to the presence of *Phytophthora ramorum* and restrict the interstate movement of regulated articles from those areas. Regulated articles are identified in § 301.92–2 of the regulations.

In subsequent Federal Orders, the Animal and Plant Health Inspection

Service (APHIS) expanded the list of quarantined areas to include Contra Costa, Humboldt, Lake, and San Francisco Counties, CA, as well as another portion of Curry County, OR, and expanded the list of regulated articles to include additional confirmed hosts of *P. ramorum*.

The regulations in § 301.92–10 provide treatments that may be used to qualify regulated articles for interstate movement from quarantined areas. For unprocessed wreaths, garlands, and greenery of host plants, the only approved treatment has consisted of a hot water dip for 1 hour at a sustained temperature of at least 160 °F. However, this treatment is not a viable option for treating leaves from the California bay laurel (*Umbellularia californica*), as it ruins the leaves for their intended use as a dried spice.

On February 8, 2005, we published in the **Federal Register** (70 FR 6596–6598, Docket No. 04–092–1) a proposal to amend the Plant Protection and Quarantine Treatment Manual (PPQ Treatment Manual), which was incorporated by reference in the Code of Federal Regulations, to allow leaves of the California bay laurel to be treated with vacuum heat before being moved interstate from any area quarantined because of *P. ramorum*. In addition to adding this vacuum heat treatment schedule, which we would have designated as T101-m-2–1–2, to the PPQ Treatment Manual, we also proposed amending the PPQ Treatment Manual’s incorporation by reference in 7 CFR part 300.1 to reflect the date of the treatment’s inclusion in the manual, and the list of accepted treatments in § 301.92–10 to include any treatments authorized for use on *P. ramorum* that are listed in the PPQ Treatment Manual.

We solicited comments concerning our proposal for 60 days ending April 11, 2005. We received one comment by that date, from a spice trade association. The commenter was in favor of amending the regulations to allow California bay laurel leaves to be treated with vacuum heat before moving interstate from areas quarantined because of *P. ramorum*.

In the proposed rule, we proposed adding the vacuum heat treatment for bay leaves to the PPQ Treatment Manual. However on June 7, 2005, we published in the **Federal Register** a final rule (70 FR 33264–33326, Docket No. 02–019–1) that removed the PPQ Treatment Manual’s incorporation by reference and relocated the portions of the PPQ Treatment Manual that prescribe treatment schedules, instructions for administering the treatments, and requirements for

certification of facilities that administer the treatments to 7 CFR part 305, “Phytosanitary Treatments.” Therefore, in this final rule, we are adding the vacuum heat treatment for bay leaves to part 305 rather than the PPQ Treatment Manual.

In addition, in the proposed rule, the vacuum heat treatment for use on bay leaves was given the designation T101-m-2–1–2, but the T101 numbering series is used to refer to fumigation treatments. As the vacuum heat treatment described in the proposed rule and this final rule is not a fumigation treatment, we are designating the treatment as T111-a-1 and are adding it to the regulations as a new § 305.29 in the “Heat Treatments” subpart.

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

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. Immediate implementation of this rule is necessary to provide relief to those persons who are adversely affected by restrictions we no longer find warranted. The regulations have required that the greenery of *P. ramorum* host plants, which include California bay laurel, grown in a quarantined area be treated with a hot water dip before being moved interstate from a quarantined area. Making this rule effective immediately will provide entities that produce and market spices with an alternative treatment for bay laurel leaves produced in areas quarantined because of *P. ramorum* that will not render the leaves unsuitable for their intended use as a dried spice. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

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

This final rule amends the phytosanitary treatments regulations to allow leaves of the California bay laurel to be treated with vacuum heat before being moved interstate from any area quarantined because of *P. ramorum*. This action will provide an alternative