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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS-2009-0023]

RIN 0579-AC96

Citrus Canker; Movement of Fruit From Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the citrus canker regulations to modify the conditions under which fruit may be moved interstate from a quarantined area. Under this proposed rule, we would eliminate the requirement that each lot of finished fruit be inspected at the packinghouse and found to be free of visible symptoms of citrus canker, and we would remove the current prohibition on the movement of fruit from a quarantined area to commercial citrus-producing States. We would continue to require fruit moved interstate from a quarantined area to be treated with an approved disinfectant and to be packed in a commercial packinghouse that operates under a compliance agreement. These proposed changes would relieve some restrictions on the interstate movement of fresh citrus fruit from quarantined areas while maintaining conditions that would prevent the artificial spread of citrus canker.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0023> to submit or view comments and to view supporting and related materials available electronically.
- Postal Mail/Commercial Delivery: Please send two copies of your comment to Docket No. APHIS-2009-0023, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2009-0023.

Reading Room: 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Poe, Senior Operations Officer, Emergency and Domestic Programs, Plant Protection and Quarantine, APHIS, 4700 River Road Unit 137, Riverdale, MD 20737-1231; (301) 734-4387.

SUPPLEMENTARY INFORMATION:

Background

Citrus canker is a plant disease caused by the bacterium Xanthomonas citri subsp. citri (referred to below as Xcc) that affects plants and plant parts, including fresh fruit, of citrus and citrus relatives (Family Rutaceae). Citrus canker can cause defoliation and other serious damage to the leaves and twigs of susceptible plants. It can also cause lesions on the fruit of infected plants, which render the fruit unmarketable, and cause infected fruit to drop from the trees before reaching maturity. The A (Asiatic) strain of citrus canker can infect susceptible plants rapidly and lead to extensive economic losses in commercial citrus-producing areas. Citrus canker is only known to be present in the United States in the State of Florida.

The regulations to prevent the interstate spread of citrus canker are contained in "Subpart–Citrus Canker" (7 CFR 301.75-1 through 301.75-14, referred to below as the regulations). The regulations restrict the interstate movement of regulated articles from and through areas quarantined because of citrus canker and provide, among other things, conditions under which regulated fruit may be moved into, through, and from quarantined areas for packing.

The conditions for the interstate movement of regulated fruit produced in a quarantined area in § 301.75-7(a) are currently as follows:

- Every lot of fruit to be moved interstate must be inspected by an Animal and Plant Health Inspection Service (APHIS) employee at a commercial packinghouse for symptoms of citrus canker. Any lot found to contain fruit with visible symptoms of citrus canker will be ineligible for interstate movement from the quarantined area. The number of fruit to be inspected will be the quantity that is sufficient to detect, with a 95 percent level of

confidence, any lot of fruit containing 0.38 percent or more fruit with visible canker lesions. A lot of fruit that is inspected and found to be ineligible for interstate movement may not be reconditioned and submitted for reinspection.

- The owner or operator of any commercial packinghouse that wishes to move citrus fruit interstate from the quarantined area must enter into a compliance agreement with APHIS in accordance with § 301.75-13.
- The regulated fruit was treated with an approved disinfectant in accordance with § 301.75-11(a).
- The regulated fruit is free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit.
- Each lot of regulated fruit found to be eligible for interstate movement must be accompanied by a limited permit issued in accordance with § 301.75-12. Regulated fruit to be moved interstate must be packaged in boxes or other containers that are approved by APHIS and that are used exclusively for regulated fruit that is eligible for interstate movement. The boxes or other containers in which the fruit is packaged, and any shipping documents accompanying the boxes or other containers, must be clearly marked with a statement indicating that they may not be distributed in American Samoa, Arizona, California, Guam, Hawaii, Louisiana, Commonwealth of the Northern Mariana Islands, Puerto Rico, Texas, and the U.S. Virgin Islands. (These are the commercial citrus-producing areas listed in § 301.75-5; we refer to them in this document as commercial citrus-producing States.)

In a final rule¹ effective and published in the Federal Register on November 19, 2007 (72 FR 65172-65204, Docket No. APHIS-2007-0022), we amended the regulations governing the interstate movement of regulated fruit from a quarantined area to establish these conditions. That final rule eliminated a requirement that the groves in which fruit to be moved interstate is produced be inspected and found free of citrus canker. Instead, we added the packinghouse inspection requirement mentioned earlier. We retained the other requirements that had been in the regulations, including the requirement that the fruit be treated with a surface disinfectant and the prohibition on the movement of fruit from a quarantined area into commercial citrus-producing States listed in § 301.75-5.

We established those conditions based on the conclusions of a pest risk assessment (PRA) and risk management analysis (RMA) prepared for that rulemaking. The PRA concluded that asymptomatic, commercially produced citrus fruit, treated with a disinfectant and subject to other mitigations, is not epidemiologically significant as a pathway for the introduction and spread of citrus canker.

The RMA examined the risks associated with both symptomatic and asymptomatic fruit and concluded that the introduction and spread of Xcc into other States through the movement of commercially packed fresh citrus fruit from quarantined areas is unlikely. In addition, the RMA concluded that a phytosanitary inspection would ensure, with high confidence, that few shipped fruit would have symptoms of citrus canker disease. However, the RMA also concluded that the evidence available at that time was not sufficient to support a determination that fresh citrus fruit

¹ To view the final rule, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0022>.

produced in an Xcc-infested grove cannot serve as a pathway for the introduction of Xcc into new areas, thus necessitating the prohibition on movement of fruit into commercial citrus-producing States.

In our responses to public comments in the Background section of the November 2007 final rule, we stated: "If, in the future, evidence is developed to support a determination that commercially packed citrus fruit (both symptomatic and asymptomatic) is not an epidemiologically significant² pathway for the introduction and spread of citrus canker, we would undertake rulemaking to amend our regulations accordingly."

New Evidence Regarding the Potential of the Movement of Fruit to Spread Citrus Canker

Since the publication of the final rule, two publications have provided additional evidence regarding the potential of fruit to serve as a pathway for the introduction and spread of citrus canker. This new evidence addresses key uncertainties and caused us to revisit our previous findings. The first article, by Gottwald *et al.* (2009),³ documents research on the survival of Xcc on commercially produced and packed citrus fruit and the likelihood that such fruit could serve as a mechanism to spread the disease. The second article, by

² The term "epidemiologically significant" refers to the minimum conditions required for introduction of a disease into an unaffected area. Our judgment of whether fruit is an epidemiologically significant pathway for disease transmission is based on the likelihood that the fruit itself will be infected with the disease, that the infection will occur in a way or at a level sufficient for transmission of the disease, and that such an infected fruit will encounter the biological conditions required for transmission of the disease.

³ Gottwald, T., Graham, J., Bock, C., Bonn, G., Civerolo, E., Irey, M., Leite, R., López, M. M., McCollum, G., Parker, P., Ramallo, J., Riley, T., Schubert, T., Stein, B., and Taylor, E. (2009). The epidemiological significance of post-packinghouse survival of *Xanthomonas citri* subsp. *citri* for dissemination of Asiatic citrus canker via infected fruit. Crop Protection 28, 508-524.

Shiotani et al. (2009),⁴ documents research on the survival of Xcc on commercially produced mandarin fruits and the likelihood of spread of Xcc to trees from harvested mandarins.

Accordingly, we have prepared updates to the PRA and RMA that accompanied the November 2007 final rule. These documents, and the November 2007 PRA and RMA that they update, are available on the Regulations.gov Web site and in our reading room (see ADDRESSES above) and may be obtained from the person listed under FOR FURTHER INFORMATION CONTACT.

The updated PRA, titled "An Updated Evaluation of Citrus Fruit (Citrus spp.) as a Pathway for the Introduction of Citrus Canker Disease (Xanthomonas citri subsp. citri)" (March 2009), examines the information presented in Gottwald et al. (2009) and Shiotani et al. (2009) in the context of the earlier PRA. Based on the evidence presented in both the November 2007 PRA and the two new publications, the updated PRA concludes that asymptomatic fruit (treated or untreated) is not epidemiologically significant as a pathway for introducing citrus canker. It further concludes that symptomatic fruit subjected to a packinghouse process that includes washing with disinfectants is also not epidemiologically significant as a pathway for introducing citrus canker.

These conclusions led us to prepare a supplemental RMA, titled "Movement of Commercially Packed Citrus Fruit from Citrus Canker Disease Quarantine Area; Supplemental Risk Management Analysis" (May 2009). The supplemental RMA takes into account the conclusions of the updated PRA as well as the evidence and discussion presented in the

⁴ Shiotani, H., Uematsu, H., Tsukamoto, T., Shimizu, Y., Ueda, K., Mizuno, A. & Sato, S. (2009). Survival and dispersal of Xanthomonas citri pv. citri from infected Satsuma mandarin fruit. Crop Protection 28, 19-23.

November 2007 RMA. Like the November 2007 RMA, the supplemental RMA was submitted for peer review, in accordance with the Office of Management and Budget's bulletin on peer review. All the materials associated with the peer review on the supplemental RMA, including the peer reviewers' comments and our responses, are available at http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml. The peer reviewers' comments were considered in developing the supplemental RMA.

The supplemental RMA examines key findings from the publications mentioned earlier. These include:

- Post-harvest treatments reduce the viability of bacteria on fruit;
- The viability of bacteria on fruit diminishes after it is harvested;
- The low potential for spread from fruit to suitable hosts has now been reported by several sources;
- Rinds of infected fruit are unlikely to provide inoculum for disease if they have been discarded in the field at least 8 days; and
- Fruit parts, even those that are in direct contact with susceptible trees, are unlikely to spread the disease.

The supplemental RMA concludes that multiple lines of evidence, including, but not limited to, evidence from the two recent studies and the November 2007 RMA, indicate that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc, i.e.:

- Disease management practices in the grove reduce, but do not eliminate, Xcc populations.

- Commercially produced fruit harvested in areas where Xcc exists may be visibly infected or the fruit may carry the pathogen either on its surface or in wounds.
- Citrus canker disease development between harvest and packinghouse, via wounding for example, is not likely.
- Procedures for cleaning and disinfecting fruit are routinely applied by packinghouses.
- The individual efficacy of these procedures for removing or destroying Xcc may not be known in detail, but the effect of packinghouse treatments reduces the prevalence of viable Xcc and therefore the level of inoculum associated with commercially packed fresh citrus fruit.
- Packinghouse processing that includes a disinfectant treatment further reduces amounts of Xcc inoculum on infected or contaminated fruit.
- The viability of bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested.
- The viability of Xcc bacteria that survive the packing process will further diminish during shipping
- Epiphytic populations of Xcc may aid in pathogen dispersal, but substantial evidence indicates that bacterial populations do not infect intact mature fruit.
- Evidence indicates that wounds on harvested fruit containing Xcc inoculum do not lead to citrus canker lesion development, and Xcc populations generally decline rapidly, although wounds might occasionally retain Xcc populations that decline more slowly.
- The cool temperatures at which citrus fruit are stored and shipped and the duration of storage reduce the ability of Xcc to reproduce and cause infection.

- As a condition for successful establishment, Xcc, in amounts sufficient to cause infection, must encounter not only an environment with a conducive temperature, relative humidity, moisture, and wind events for infection, but also must encounter host plant tissue that is either at a susceptible growth stage or is wounded and then must successfully enter this tissue.
- Despite substantial international trade between Xcc-infected and noninfected countries, there is no authenticated record of movement of diseased fruit or seeds resulting in the introduction of Xcc to new areas.

Evaluation of Risk Management Options

In light of this evidence, the supplemental RMA considers five risk management options for the interstate movement of commercially packed citrus fruit from areas quarantined for citrus canker:

- Option 1: Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, without packinghouse treatment with a disinfectant.
- Option 2: Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, subject to packinghouse treatment with an APHIS-approved disinfectant, but without the current inspection requirement.
- Option 3: Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States except commercial citrus-producing States, subject to packinghouse treatment of citrus fruit with an APHIS-approved disinfectant treatment; and, allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, including commercial citrus-producing States, subject to packinghouse

treatment with an APHIS-approved disinfectant treatment and APHIS inspection for symptoms of citrus canker.

- Option 4: Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States other than commercial citrus-producing States, subject to packinghouse treatment with an APHIS-approved disinfectant.
- Option 5: Leave the current regulations for the interstate movement of citrus fruit from areas quarantined for citrus canker unchanged.

Each option was considered within the context of available scientific evidence. Option 1 would allow unrestricted distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, without packinghouse treatment with a disinfectant. However, the updated PRA and the supplemental RMA limit their conclusion that fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc to fruit that has been treated with a disinfectant. This conclusion is consistent with the Gottwald et al. (2009) article, which concludes that packinghouse-disinfested, citrus fruit with canker lesions are an unlikely pathway through which Xcc inoculum might lead to infection and Xcc establishment in new areas.

In addition, both of the recent articles examined in the updated PRA and the supplemental RMA included research on the issue of transmission of Xcc from infected fruit to nearby citrus plants. All but one of the situations reported in these articles found no transmission of Xcc to citrus plants in circumstances designed to allow for such transmission. Gottwald et al. (2009) reported one transmission of citrus canker from untreated, highly infected fruit to susceptible plants in what the paper characterized as "a highly contrived situation designed to

provide every possible opportunity for dispersal of Xcc." The situation included fruit selected specifically for their high level of canker infection, subjected to no post-harvest treatment or processing, placed next to grapefruit seedlings (considered highly susceptible to Xcc infection), and subjected to artificial wind and rain conditions. An injured grapefruit seedling immediately adjacent to the infested fruit was infected under these conditions. It is highly improbable that the conditions under which Xcc was transmitted from the untreated fruit would occur in any area; however, the experiment demonstrates that the transmission of canker from untreated fruit is possible. Therefore, we determined that movement of fruit from quarantined areas without disinfectant treatment and with no other phytosanitary mitigations was not justified by the available scientific evidence. We welcome public comment on this determination.

Option 5 is the most restrictive option that we considered. It would leave the current regulations in place and unchanged, including both the requirement for packinghouse inspection for symptoms of citrus canker and the prohibition on the movement of fruit to commercial citrus-producing States. This option would not take into account the evidence in the recent articles cited in the updated PRA and the supplemental RMA. This evidence establishes with a greater degree of certainty than was previously indicated that commercially packed fruit that is treated with an APHIS-approved disinfectant is not an epidemiologically significant pathway for the transmission of citrus canker, meaning that some phytosanitary mitigations currently included in the regulations are no longer necessary to prevent the spread of citrus canker from quarantined areas via the movement of fruit. Consequently, Options 2, 3, and 4 were evaluated and Options 1 and 5 were no longer considered.

Option 2 would allow commercially packed fruit treated with an APHIS-approved disinfectant to move from a quarantined area to any State, including commercial citrus-producing States, but would not include the current inspection requirement.

Options 3 and 4 require disinfectant treatment and include additional phytosanitary measures to address any remaining uncertainty regarding the epidemiological significance of commercially packed fruit as a pathway for the transmission of citrus canker. Option 3 would prohibit the distribution of fruit to commercial citrus-producing States unless it is inspected for symptoms of citrus canker, using the same inspection process currently described in paragraph (a)(1) of § 301.75-7. Option 4 would not include the inspection requirement but would continue to prohibit the distribution of all fruit to commercial citrus-producing States.

After considering the evidence presented in the updated PRA and the supplemental RMA and the conclusions of those documents, we have determined that currently available scientific evidence provides additional certainty that commercially packed, treated fruit is not an epidemiologically significant pathway for the spread of citrus canker. Therefore, no mitigations beyond treatment with an APHIS-approved disinfectant are necessary. Accordingly, in this document, we are proposing to implement Option 2.

Pretreatment Detergent Wash

We also considered whether to change our current fruit disinfection treatments in § 301.75-11 in light of findings in Gottwald *et al.* (2009). Paragraph (a) of § 301.75-11 currently requires fruit moved interstate from a quarantined area to be treated, in a commercial packinghouse operating under a compliance agreement, in at least one of the following ways:

- The regulated fruit must be thoroughly wetted for at least 2 minutes with a solution containing 200 parts per million sodium hypochlorite, with the solution maintained at a pH of 6.0 to 7.5.
- The regulated fruit must be thoroughly wetted with a solution containing sodium o-phenyl phenate (SOPP) at a concentration of 1.86 to 2.0 percent of the total solution, for 45 seconds if the solution has sufficient soap or detergent to cause a visible foaming action or for 1 minute if the solution does not contain sufficient soap to cause a visible foaming action.
- The regulated fruit must be thoroughly wetted for at least 1 minute with a solution containing 85 parts per million peroxyacetic acid.

Gottwald et al. (2009) presents evidence that "suggest[s] that effectiveness of packing line decontamination can be increased by using prewashing treatment that includes detergent, (such as SOPP) to remove dirt and debris that reduce the effectiveness of the disinfectants." (Shiotani et al. (2009) did not address this issue.) The supplemental RMA concludes, as noted earlier, that packinghouse processing that includes prewashing fruit with detergent over brushes followed by a disinfectant treatment further reduces already epidemiologically insignificant amounts of *Xcc* inoculum on infected or contaminated fruit. Accordingly, we considered whether to change our treatment requirements to incorporate a pretreatment detergent wash requirement in addition to the approved disinfectant treatments listed earlier.

Various studies have demonstrated the effectiveness of the currently approved disinfectants in reducing numbers of *Xcc* cells or similar bacteria to low or undetectable levels, as discussed in the November 2007 RMA. The overall results of the pretreatment detergent wash

experiments in Gottwald *et al.* (2009) were inconclusive. In the experiment in which the pretreatment detergent wash increased the effectiveness of the chlorine treatment, the treatment used was not equivalent to any of the APHIS-approved treatments listed earlier. In the other experiment, the treatment was equivalent, but the pretreatment detergent wash did not significantly increase the effectiveness of the treatment.

In addition, the updated PRA and supplemental RMA conclude that the viability of Xcc bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested; the viability of Xcc bacteria that survive the packing process will further diminish during shipping; and evidence indicates that wounds on harvested fruit containing Xcc inoculum do not lead to citrus canker lesion development, and Xcc populations generally decline rapidly, although wounds might occasionally retain Xcc populations that decline more slowly. The risk associated with bacteria that survive treatment is additionally mitigated by other steps in the commercial packing and distribution process.

Taking all the relevant evidence into account, we have determined that it is not necessary to amend the regulations to require a pretreatment detergent wash in addition to the disinfectant treatment. The current disinfectant treatments are an adequate mitigation to ensure that fruit is not an epidemiologically significant pathway for Xcc, especially when considering other aspects of the epidemiological significance of Xcc that are better characterized by the new evidence.

Proposed Changes to the Regulations Governing the Interstate Movement of Fruit

As noted earlier, the regulations governing the interstate movement of regulated fruit produced in a quarantined area are set out in paragraph (a) of § 301.75-7. Reflecting our choice of Option 2, we are proposing to remove the requirements in paragraphs (a)(1) and (a)(6), which respectively describe the current fruit inspection process and state that a lot of fruit that is determined to be ineligible for interstate movement through the inspection process may not be reconditioned and submitted for reinspection.

We are also proposing to remove the requirements in paragraph (a)(5), which requires a limited permit and marking of the fruit's packaging to prevent its movement to commercial citrus-producing States. The current introductory text of paragraph (a) in § 301.75-7 refers to movement of fruit into any area of the United States except commercial citrus-producing areas. We would amend this introductory text to indicate that regulated fruit may move interstate with a certificate issued and attached in accordance with § 301.75-12. Because we would remove the current distribution restrictions, a certificate, which allows unrestricted movement, would be the appropriate document to accompany regulated fruit moved interstate from the quarantined area under the proposed regulations.

Paragraph (a)(2) requires the owner or operator of any commercial packinghouse that wishes to move citrus fruit interstate from the quarantined area to enter into a compliance agreement with APHIS in accordance with § 301.75-13. We are proposing to move this requirement to paragraph (a)(1) and to restate it slightly to emphasize that the fruit must be packed in a commercial packinghouse. The emphasis on packing in a commercial packinghouse would ensure that the regulations are consistent with the conclusions of the updated PRA and the

supplemental RMA, which evaluate the risk of spread of citrus canker via commercially packed fruit specifically. Under this proposal, paragraph (a)(1) of § 301.75-7 would state that regulated fruit must be packed in a commercial packinghouse whose owner or operator has entered into a compliance agreement with APHIS in accordance with § 301.75-13.

The term "commercial packinghouse" is defined in § 301.75-1 as an establishment in which space and equipment are maintained for the primary purpose of packing citrus fruit for commercial sale. The conclusions of the supplemental RMA refer specifically to disinfected fruit; accordingly, we are proposing to amend this definition to refer to equipment maintained for the primary purpose of disinfecting and packing fruit.

In addition, under the current definition of commercial packinghouse, a commercial packinghouse must be registered as a packinghouse with the State in which it operates or hold a business license for treating and packing fruit. However, part of this definition is in error; there is no business license available for treating and packing fruit in the citrus canker quarantined area. Rather, there are State licensing, registration, and certification provisions for commercial packinghouses, and each of these provisions includes requirements that the packinghouse must fulfill in order to be licensed, certified, or registered as a commercial packinghouse. Therefore, we are proposing to amend the commercial packinghouse definition to require that a commercial packinghouse be licensed, registered, or certified with the State in which it operates and meet all the requirements for the license, registration, or certification that it holds.

Proposed paragraph (a)(2) of § 301.75-7 would require the regulated fruit to be treated in accordance with § 301.75-11(a). This requirement is currently contained in paragraph (a)(3).

Proposed paragraph (a)(3) would require the regulated fruit to be free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit. This requirement is currently contained in paragraph (a)(4). We are proposing to retain this requirement, which is necessary because other plant parts pose different risks than fruit does; canker lesions on leaves, for example, typically have much higher bacterial populations than canker lesions on fruit.

Under this proposed rule, APHIS inspectors would no longer be on site at packinghouses to enforce the requirements for treatment and removal of leaves, twigs, and other plant parts. We would require that these activities be conducted in accordance with the regulations in our compliance agreements with commercial packinghouses, and spot checks would be conducted to ensure that treatment is being performed properly and that no leaves, twigs, or other plant parts are being included in containers of fruit moved interstate.

As noted earlier, we are proposing to remove the requirements related to packaging fruit moved interstate, under which only fruit that met the requirements of the regulations could be packaged in boxes or other containers bearing a statement prohibiting their distribution to commercial citrus-producing States, because we are proposing to remove the distribution restrictions that made those packaging requirements necessary. It is a common business practice in Florida for businesses to buy commercially packed and treated fruit and repackage it for interstate movement before the fruit is ultimately moved interstate from Florida. Under this proposed rule, the repackaged fruit would not be moved with its original certificate, which would have been attached to the container in which the fruit was originally packed or to the waybill originally accompanying the fruit in accordance with § 301.75-12. However, fruit moved

interstate would need to be moved with a certificate to allow us to verify that it was moved in accordance with the proposed regulations.

To address this issue, we are proposing to include a new paragraph (a)(4). This paragraph would state that, if fruit is repackaged after being packed in a commercial packinghouse and before it is moved interstate from the quarantined area, the person that repackages the fruit must enter into a compliance agreement with APHIS in accordance with § 301.75-13 and issue and attach a certificate for the interstate movement of the fruit in accordance with § 301.75-12.

In current § 301.75-7, paragraph (c) contains requirements for the interstate movement of fruit from a quarantined area when that fruit was not produced in the quarantined area but was moved there for packing. Under paragraph (c)(1), such fruit may be moved to States other than commercial citrus-producing States, under conditions similar to those in current paragraph (a), or the fruit may be moved to any State (including commercial citrus-producing States) under the conditions specified in under paragraph (c)(2). These conditions include covering the fruit while it is in transit, keeping it separate from fruit that is produced in the quarantined area and packed in the packinghouse, and otherwise preventing its exposure to citrus canker. The fruit must also be treated in accordance with § 301.75-11(a).

We evaluated these conditions in light of the updated PRA and the supplemental RMA and the changes we are proposing. The supplemental RMA indicates that it is not necessary to separate fruit produced in a quarantined area from fruit not produced in a quarantined area, as substantial evidence indicates that bacterial populations of Xcc on harvested fruit do not infect intact mature fruit. Although paragraph (c)(2) does not require fruit moved to a quarantined area

for packing and intended to be moved to commercial citrus-producing States to be packed in a commercial packinghouse, as would be required under proposed paragraph (a)(1) of § 301.75-7, the provisions for separation of fruit, disinfection of equipment, and disposal of litter in paragraph (c)(2) effectively limit its applicability to fruit packed in commercial packinghouses. Paragraph (c)(2) currently contains a requirement for treating fruit moved interstate, as would be required under proposed paragraph (a)(2). In addition, removing leaves, twigs, and other plant material from packed fruit, as would be required in proposed paragraph (a)(3), is a typical packing practice in commercial packinghouses.

Given these considerations, we believe that it is no longer necessary to provide separate conditions for the interstate movement of fruit produced in a quarantined area and fruit that is not produced in a quarantined area but is moved into a quarantined area for packing. Therefore, this proposal would remove paragraph (c) and amend the introductory text of paragraph (a) to indicate that paragraph (a) provides conditions for the interstate movement of all regulated fruit from citrus canker quarantined areas.

Paragraph (b) in § 301.75-7 states that regulated fruit produced in a quarantined area that is not eligible for movement under paragraph (a) may be moved interstate only for immediate export. We are proposing to amend this paragraph to indicate that any regulated fruit in a quarantined area, whether produced in the area or moved to the area for packing, that is not eligible for interstate movement could only be moved for immediate export.

Section 301.75-4 of the regulations sets out the quarantined areas for citrus canker. Within § 301.75-4, paragraph (d) sets out conditions for designating an area less than an entire State as a quarantined area. Some of these conditions concern the movement of fruit. We are

proposing to retain most of the conditions for the intrastate movement of fruit in paragraphs (d)(2)(i) and (ii), as they contain requirements intended to prevent intrastate transmission of citrus canker via plant parts other than fruit and via equipment. The first sentence of paragraph (d)(2)(ii)(D), though, requires regulated fruit moved intrastate for packing to be stored separately from and have no contact with fruit eligible for movement to commercial citrus-producing States. As discussed earlier, this provision is no longer necessary, and we are therefore proposing to remove it.

We are also proposing to remove paragraph (d)(6), which requires that, in addition to meeting the conditions in § 301.75-7(a), fruit moved interstate from a quarantined area less than an entire State originate from a grove in which no plant parts infected with citrus canker were found in the 2 years before interstate movement and in which any exposed plants in the grove at high risk for developing citrus canker have been destroyed. This provision is intended to reduce the prevalence of citrus canker in fruit to be moved interstate. Because we have determined that fruit that meets the requirements of proposed § 301.75-7(a) is not an epidemiologically significant pathway for the transmission of citrus canker, this additional requirement is not necessary. Accordingly, we are proposing to remove paragraph (d)(6).

Under § 412(a) of the Plant Protection Act (7 U.S.C. § 7712), the Secretary of Agriculture may prohibit or restrict the interstate movement of any plant or plant product if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination within the United States of a plant pest or noxious weed. Based on our supplemental RMA, APHIS has concluded that commercially packed citrus fruit treated with an APHIS-approved disinfectant is not an epidemiologically significant pathway for the dissemination of citrus

canker within the United States. Accordingly, APHIS has determined that it is not necessary to prohibit the interstate movement of fruit from citrus canker quarantined areas that is commercially packed and treated with an APHIS-approved disinfectant in order to prevent the dissemination within the United States of a plant pest or noxious weed. This determination is based on the findings of the updated PRA and the supplemental RMA referred to earlier in this document and our judgment that the application of the measures that would be required under proposed § 301.75-7(a) would prevent the dissemination of plant pests within the United States.

Although this proposed rule would amend only the domestic citrus canker quarantine regulations, we would in the future consider the risk management strategy proposed here to be suitable to mitigate against citrus canker in fruit imported from foreign countries affected with citrus canker. However, the national plant protection organization of such a country would need to submit a request that we do so. A country requesting to be able to use this framework to export citrus to us would have to demonstrate the ability to perform the required treatments; it would also be required to have a bilateral workplan in place with APHIS. In addition, there may be other citrus pests in foreign citrus production areas whose risk would need to be mitigated separately from the risk posed by citrus canker; a request to export citrus from a canker-affected country would need to incorporate the risk management strategy for citrus canker that we propose here into a risk management approach that addresses the total citrus pest complex present in that country. For that reason, we would complete a separate pest risk analysis for such an action.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Order 12866, and an initial regulatory flexibility analysis that examines the potential economic effects of this interim rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below.

Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

We are proposing to amend the citrus canker regulations to modify the conditions under which fruit may be moved interstate from a quarantined area. Under this proposed rule, we would eliminate the requirement that each lot of finished fruit be inspected at the packinghouse and found to be free of visible symptoms of citrus canker, and we would remove the current prohibition on the movement of fruit from a quarantined area to commercial citrus-producing States. We would continue to require fruit moved interstate from a quarantined area to be treated with an approved disinfectant and to be packed in a commercial packinghouse that operates under a compliance agreement. These proposed changes would relieve some restrictions on the interstate movement of fresh citrus fruit from quarantined areas while maintaining conditions that would prevent the artificial spread of citrus canker.

In the November 2007 final rule, we amended the regulations governing the interstate movement of regulated fruit from a quarantined area. That final rule removed the grove inspection requirement whereby fresh citrus fruit to be moved interstate was to be inspected by APHIS and found to be free of citrus canker. Instead, we added a requirement for packinghouse inspection of fresh citrus for symptoms of citrus canker. We retained the other requirements that had been in the regulations, including the requirement that the fruit be treated with a surface disinfectant and the prohibition on the movement of fruit from a quarantined area into commercial citrus-producing States listed in § 301.75-5. All components associated with the changes in regulations were based on scientific findings as outlined in the PRA and RMA prepared for that rulemaking.

New scientific evidence has led APHIS to prepare an updated PRA and a supplemental RMA. These documents indicate that less stringent regulations would offer the same level of protection against the spread of citrus canker while lessening some of the economic burden associated with compliance under the current regulations. By removing the requirement that fruit to be moved interstate be inspected and found to be free of citrus canker symptoms, the proposed rule would allow for the long-term preservation of fresh citrus movement to the domestic market by Florida's commercial packinghouses and growers. (We use the term "domestic market" to mean all States except Florida.)

Under the current regulations, approximately 4.7 percent of the lots of fresh grapefruit, 1.2 percent of the lots of fresh oranges and temples, and 0.2 percent of the lots of fresh tangerines and tangelos intended for the domestic market were rejected during the 2008-09 season due to the presence of citrus canker, as found during APHIS inspection at the

packinghouse. If APHIS inspectors find citrus canker on one piece of citrus fruit during their inspection, the entire lot is prohibited from interstate movement. Furthermore, it is also highly likely that some producers, after assessing whether the prevalence of citrus canker in their groves is low enough for their fruit to pass inspection after packinghouse grading and culling, may consider alternative markets for their citrus rather than risk costly packing charges associated with the rejected lots.

While the rejected lots of the 2008-09 season were successfully diverted for processing or to fresh fruit markets within Florida or outside the United States, affected citrus producers and commercial packinghouses do incur revenue losses due to the product diversion. The cost of producing citrus fruit intended for the fresh market is greater than the cost of production for the processed market, where the physical appearance of the fruit is not important; the value of citrus on the processed market is relatively low compared to the value of citrus sold on the fresh market.

As citrus canker continues to spread throughout Florida, the proportion of fruit diverted to other markets because of rejected lots will increase. Citrus growers will only maintain self-surveys and best management field practices for citrus canker that are necessary to produce fruit for the domestic fresh citrus market as long as the expected net return from the fresh fruit sales is greater than the expected net return from sales for processing or from sales of fresh fruit within Florida or in foreign markets. The greater the likelihood that a lot may be rejected because of fruit found to have citrus canker symptoms, thereby resulting in elimination charges and price discounts, the less likely producers will choose to bear the higher costs of self-surveys and best management practices.

In an interim rule effective and published on August 1, 2006 (71 FR 43345-43352, Docket No. APHIS-2006-0114), we amended the regulations to designate the entire State of Florida as a quarantined area for citrus canker. This action resulted in restrictions on the movement of all citrus fruit from the State of Florida, including a prohibition on distributing such fruit to commercial citrus-producing States. This proposed rule would also allow for the renewal of fresh citrus market access to other commercial citrus-producing States. Prior to implementation of the August 2006 interim rule, Florida shipped an average of 106,000 4/5-bushel cartons of fresh grapefruit, 209,000 4/5-bushel cartons of fresh oranges and temples, and 1 million 4/5-bushel cartons of fresh tangerines and tangelos to other commercial citrus-producing States.⁵ Approximately 5.7 percent of Florida domestic fresh fruit shipments (nearly 4 percent of all shipments, including exports) were transported to other commercial citrus-producing States during the 2004-05 season, the final season in which Florida fresh citrus was permitted movement into these States. California received about 3 percent of Florida's domestic fresh citrus shipments during the 2004-05 season. While fresh citrus shipments to other commercial citrus-producing States generally accounted for less than 6 percent of Florida's domestic market supply, that State's producers and citrus packers of fresh tangerines and tangelos found lucrative markets for their products in California, Texas, and Louisiana, shipping between 12 and 15 percent of total domestic fresh shipments to these States.

U.S. consumers other than those in Florida would benefit from an increased supply of fresh citrus because of this rule, especially fresh grapefruit. Florida is the largest supplier of fresh grapefruit, with an average domestic fresh market supply of more than 6 million 4/5-bushel

⁵ Based on 5-year averages of shipments during the 2003-04 through 2007-08 seasons.

cartons. As grapefruit are more likely to face rejection than other, less susceptible citrus, domestic consumers will have increasingly limited access to fresh grapefruit under the current regulations, particularly if Florida's bearing acreage continues to decline on average by 11 percent annually.

According to APHIS estimates, Federal expenditures on commercial packinghouse inspections of fresh fruit intended for domestic markets range from \$8.95 million to \$9.85 million per season. Under the proposed rule, commercial citrus packinghouse inspections by APHIS of fresh citrus intended for the domestic market for symptoms of citrus canker would no longer be required, resulting in significant Federal savings.

The proposed rule would also likely result in a lower supply of fresh citrus for Florida consumers. APHIS data indicate that nearly 30 percent of rejected fresh citrus shipments originally intended for the domestic market were redirected to markets within Florida. However, this same fresh citrus fruit diverted to markets within Florida represented only about 2 percent of all fresh citrus shipped within the State. The benefits of long-term preservation of the domestic market for Florida fresh citrus, less restrictive market access, costs savings of foregone inspections of fresh fruit for symptoms of citrus canker, and savings on packinghouse charges are expected to outweigh the additional costs imposed by the proposed changes to the regulations. The science-based revisions to the regulations would continue to prevent the spread of citrus canker to other States, including commercial citrus-producing States.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires that agencies consider the economic impact of their rules on small businesses, organizations, and governmental jurisdictions. Section 603 of the

Act requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis (IRFA) describing the expected impact of proposed rules on small entities. Sections 603(b) and 603(c) of the Act specify the content of an IRFA. In this section, we address these IRFA requirements for this proposed rule.

Reasons for Action

APHIS is taking these actions based on the determination that citrus fruit that has citrus canker symptoms and that has been treated using an APHIS-approved disinfectant is not an epidemiologically significant pathway for transmission of the disease. Citrus canker in Florida is pervasive, and eradication and quarantine zones within the State have not succeeded in controlling the spread of the disease within Florida. This action is being taken to relieve restrictions on the Florida citrus industry that we believe are no longer warranted while continuing to prevent the spread of citrus canker to other U.S. commercial citrus-producing States and territories.

The current citrus canker regulations place several restrictions on the interstate movement of citrus fruit from areas quarantined due to citrus canker, including APHIS inspection of fresh citrus intended for the domestic market, treatments, and interstate movement only under limited permit to States that do not produce citrus commercially. APHIS is proposing to implement a new protocol under which specified treatments would be required for Florida citrus shippers to move regulated fresh fruit to all States without the currently required APHIS inspection. This action would apply less restrictive measures for movement of fresh citrus from Florida while continuing to prevent the spread of citrus canker to areas free from the pest.

Objectives and Legal Basis for Proposed Rule

The objective of the proposed rule is to modify the current protocol contained in § 301.75-7 that stipulates the conditions under which fresh citrus fruit may be moved interstate from quarantined areas. Under the provisions of this proposed rule, a new mitigation strategy would eliminate the required APHIS inspection of each lot of finished fruit.

Under section 412(a) of the Plant Protection Act, the Secretary of Agriculture may prohibit or restrict the movement in interstate commerce of any plant or plant product if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination of a plant pest or noxious weed within the United States. APHIS has determined that it is not necessary to prohibit the interstate movement of fruit from citrus canker quarantined areas that is commercially packed and treated with an APHIS-approved disinfectant in order to prevent the dissemination within the United States of a plant pest or noxious weed. This determination is based on the findings of the updated PRA and the supplemental RMA referred to earlier in this document and our judgment that the application of the measures that would be required under proposed § 301.75-7(a) would prevent the dissemination of plant pests within the United States.

Description and Estimated Number of Small Entities Regulated

Florida's citrus commercial packinghouses and fresh citrus producers comprise the industries that we expect to be directly affected by this proposed rule. The small business size standards for citrus fruit packing, as identified by the Small Business Administration (SBA) based upon the North American Industry Classification System (NAICS) code 115114 (Postharvest Crop Activities) is \$6.5 million or less in annual receipts. There are currently 174 commercial packinghouses in Florida under an APHIS packinghouse compliance agreement, 56

of which are registered with the Florida Department of Agriculture and Consumer Services' Division of Fruit and Vegetables. While the classification of all of these establishments by sales volume is not available, it is estimated that approximately 40 of the 56 registered commercial packinghouses are the top-grossing citrus commercial packinghouses. The remaining packinghouses are small establishments known primarily as gift packers. At least 95 percent of Florida fresh citrus shipments are packed by the top 40 (23 percent) commercial packinghouses in the State.⁶ The Fresh Shippers Report, as reported by the Citrus Administrative Committee, details quantities of fresh citrus shipped by the top 40 shippers each season.⁷ During the 2007-08 season, annual sales for 14 of the top 40 shippers (35 percent) were below the SBA size standard of \$6.5 million. It is estimated that at least 82 percent of Florida's citrus packers, including the small gift packers, would be considered small according to the SBA size standards.

The proposed rule is also expected to positively affect producers of fresh citrus in Florida currently facing an increasing number of lots rejected at the packinghouse level each season. Packing and elimination charges for growers are higher for fruit diverted to the intrastate or export markets, or processing plants. In addition, fruit diverted to processing yields lower revenues for growers who have already borne the higher costs of producing fruit intended for the fresh market.

A majority of the Florida citrus producers that would be affected by the proposed rule are small, based on 2007 Census of Agriculture data and SBA guidelines for entities classified within the farm categories Orange Groves (NAICS 111310) and Citrus (except Orange) Groves

⁶ "Fresh Shippers Report: 2007-08 Season Through July 31, 2008," Citrus Administrative Committee, August 8, 2008. <http://www.citrusadministrativecommittee.org/>

⁷ Ibid.

(NAICS 111320). SBA classifies producers in these categories with total annual sales of not more than \$750,000 as small entities. According to 2007 Census data, there were a total of 6,061 citrus farms in Florida in 2007. Of this number, 90 percent had annual sales in 2007 of less than \$500,000, which is well below the SBA's small entity threshold of \$750,000.⁸ Any costs associated with the proposed rule are expected to be minimal, especially given the producers' gains from fewer rejections of fresh citrus lots destined for the domestic market.

Producers of fresh fruit in other commercial citrus-producing States may also be impacted by the rule to the extent that the reintroduction of Florida fresh citrus changes the supply in these States. However, APHIS does not anticipate significant increases in fresh citrus supplies into these markets as a result of this proposed rule, as indicated by historic data on Florida fresh citrus shipments. According to 2007 Census data, there were a total of 15,658 citrus farms in the United States in 2007. Of this total, 329 were located in Arizona, 7,358 in California, 884 in Hawaii, 210 in Louisiana, and 750 in Texas. In each State, at least 91 percent of all farms had annual sales in 2007 of less than \$500,000 and would be classified as small entities according to SBA guidelines.

Description and Estimate of Compliance Requirements

In general, this rule would not entail new reporting, recordkeeping, or other compliance requirements beyond those already required for shipment of Florida fresh citrus destined for domestic and export markets. The costs to packinghouses associated with certifying fruit for interstate movement are expected to be less than the costs associated with the current requirement that limited permits accompany shipments of fresh citrus from Florida that are

⁸ Source: SBA and 2007 Census of Agriculture.

moved interstate. In addition, under the current regulations, fresh citrus fruit from Florida destined for the domestic market must be packed in boxes with markings that indicate that fruit is prohibited from movement into other commercial citrus-producing States in order to obtain a limited permit. The proposed rule would eliminate the required limited permits and packaging requirements at a cost savings to packinghouses.

The annual cost of obtaining a Citrus Fruit Dealer License is less than \$25. There is no cost to register as a commercial packinghouse, but the Florida Department of Agriculture does charge inspection fees and box taxes where applicable. Of the 174 packinghouses currently operating under an APHIS compliance agreement, we estimate that fewer than 10 would need to obtain a license or registration in order to obtain a compliance agreement with APHIS and meet the requirements of the proposed regulations. .

Duplication, Overlap, and Conflict with Existing Rules and Regulations

APHIS has not identified any duplication, overlap, or conflict of the proposed rule with other Federal rules.

Regulatory Alternatives

An in depth discussion of the alternatives we considered in preparing this proposed rule may be found earlier in this document under the heading "Evaluation of Risk Management Options" as well as in the accompanying full economic analysis.

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.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the proposed amendments to the regulations providing for the interstate movement of regulated fruit from areas quarantined for citrus canker, we have prepared an environmental assessment. The environmental assessment was 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 may be viewed on the Regulations.gov Web site or in our reading room. (A link to Regulations.gov and information on the location and hours of the reading room are provided under the heading ADDRESSES at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects in 7 CFR Part 301

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

Accordingly, we propose to amend 7 CFR part 301 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 issued under Sec. 204, Title II, Public Law 106-113, 113 Stat. 1501A-293; sections 301.75-15 and 301.75-16 issued under Sec. 203, Title II, Public Law 106-224, 114 Stat. 400 (7 U.S.C. 1421 note).

2. In § 301.75-1, the definition of commercial packinghouse is revised to read as follows:

§ 301.75-1 Definitions.

* * * * *

Commercial packinghouse. An establishment in which space and equipment are maintained for the primary purpose of disinfecting and packing citrus fruit for commercial sale. A commercial packinghouse must also be licensed, registered, or certified with the State in which it operates and meet all the requirements for the license, registration, or certification that it holds.

* * * * *

§ 301.75-4 [Amended]

3. Section 301.75-4 is amended as follows:
 - a. In paragraph (d)(2)(ii)(D), by removing the first sentence.
 - b. By removing paragraph (d)(6).
4. Section 301.75-7 is revised to read as follows:

§ 301.75-7 Interstate movement of regulated fruit from a quarantined area.

(a) Regulated fruit produced in a quarantined area or moved into a quarantined area for packing may be moved interstate with a certificate issued and attached in accordance with § 301.75-12 if all of the following conditions are met:

- (1) The regulated fruit was packed in a commercial packinghouse whose owner or operator has entered into a compliance agreement with APHIS in accordance with § 301.75-13.
- (2) The regulated fruit was treated in accordance with § 301.75-11(a).
- (3) The regulated fruit is free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit.
- (4) If the fruit is repackaged after being packed in a commercial packinghouse and before it is moved interstate from the quarantined area, the person that repackages the fruit must enter into a compliance agreement with APHIS in accordance with § 301.75-13 and issue and attach a certificate for the interstate movement of the fruit in accordance with § 301.75-12.

(b) Regulated fruit that is not eligible for movement under paragraph (a) of this section may be moved interstate only for immediate export. The regulated fruit must be accompanied by a limited permit issued in accordance with § 301.75-12 and must be moved in a container sealed by APHIS directly to the port of export in accordance with the conditions of the limited permit.

(Approved by the Office of Management and Budget under control number 0579-0325)

Done in Washington, DC, this 26th day of June 2009.

Cindy Smith,

Acting Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2009-15508 Filed 06/29/2009 at 8:45 am; Publication Date: 06/30/2009]