

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 301 and 305

[Docket No. APHIS-2007-0022]

RIN 0579-AC34

Citrus Canker; Movement of Fruit From Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the citrus canker regulations to modify the conditions under which fruit may be moved interstate from a quarantined area. We are eliminating the requirement that the groves in which the fruit is produced be inspected and found free of citrus canker, and instead are requiring that every lot of fruit produced in the quarantined area be inspected by the Animal and Plant Health Inspection Service at a packinghouse operating under a compliance agreement and found to be free of visible symptoms of citrus canker. We are retaining 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. These changes will relieve some restrictions on the interstate movement of fresh citrus fruit from Florida while maintaining conditions that will help prevent the artificial spread of citrus canker.

DATES: *Effective Date:* November 19, 2007.

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 axonopodis* pv. *citri* (referred to below as *Xac*) 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 aggressive 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 §§ 301.75-1 through 301.75-14 of "Subpart—Citrus Canker" (7 CFR 301.75-1 through 301.75-17, 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. These regulations are promulgated pursuant to the Plant Protection Act (7 U.S.C. 7701 *et seq.*).

On June 21, 2007, we published in the **Federal Register** (72 FR 34180-34191, Docket No. APHIS-2007-0022) a proposal¹ to amend the citrus canker regulations by modifying the conditions under which fruit may be moved interstate from quarantined areas. We proposed to eliminate the requirement that the groves in which the fruit is produced be inspected and found free of citrus canker, and instead proposed to require that every lot of fruit produced in the quarantined area be inspected by the Animal and Plant Health Inspection Service (APHIS) at a packinghouse operating under a compliance agreement and found to be free of visible symptoms of citrus canker. We proposed to retain 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.

We solicited comments concerning our proposal for 30 days ending July 23, 2007. We subsequently reopened and extended the deadline for comments until August 7, 2007, in a document published in the **Federal Register** on July 27, 2007 (Docket No. APHIS-2007-0022, 72 FR 41239). We received 72 comments by the close of the comment period. They were from producers, exporters, researchers, and representatives of State governments. They are discussed below by topic.

¹ To view the proposed rule, the supporting analyses, and the comments we received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0022>.

Pest Risk Assessment and Risk Management Analysis

To inform the deliberations that led to the proposed rule, we prepared two documents that addressed the risk associated with the interstate movement of citrus fruit from a quarantined area: A pest risk assessment (PRA) and a risk management analysis (RMA). The PRA, which was titled "Evaluation of asymptomatic citrus fruit (*Citrus* spp.) as a pathway for the introduction of citrus canker disease (*Xanthomonas axonopodis* pv. *citri*)," considered all available evidence associated with asymptomatic citrus fruit as a pathway for the introduction of citrus canker. The PRA concluded that asymptomatic, commercially produced citrus fruit treated with a surface disinfectant and subject to other mitigations is not epidemiologically significant² as a pathway for the introduction and spread of citrus canker. We first made this document available for comment on April 6, 2006, when we published a notice in the **Federal Register** (71 FR 17434-17435, Docket No. APHIS-2006-0045), announcing its availability for comment for 60 days; the comment period was subsequently extended to 90 days. We also submitted it for peer review in accordance with the U.S. Department of Agriculture (USDA) guidelines for peer review developed in response to the Office of Management and Budget's peer review bulletin. We received 19 comments by the end of the comment period, which we also submitted to the peer review panel members for their consideration.³ We carefully considered the comments of the public and peer reviewers, and made revisions to the analysis based on concerns they raised. The revisions did not change the conclusions of the PRA; the revised version of the PRA was provided with the proposed rule.

In light of the comments by the public and peer reviewers, it became clear that additional analysis was necessary to apply the conclusions of the PRA to the situation in Florida. In order to apply the conclusions of the PRA, we needed to extend its application to evaluate methods by which fruit⁴ could be produced, treated, inspected, packaged, and shipped without resulting in the

² We use the term "epidemiologically significant" to refer to minimum conditions required for disease transmission.

³ The original PRA and the comments we received on it can be viewed at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0045>.

⁴ Given the practical difficulties in ensuring that only asymptomatic fruit enters interstate commerce under any regulatory strategy, we refer here to host fruit in general.

spread of citrus canker to commercial citrus-producing areas. (Commercial citrus-producing areas are listed in § 301.75–5 of the regulations and are referred to in this document as commercial citrus-producing States. Those States, listed in § 301.75–5(a), are: American Samoa, Arizona, California, Florida, Guam, Hawaii, Louisiana, Northern Mariana Islands, Puerto Rico, Texas, and the U.S. Virgin Islands.)

To address the considerations described above, APHIS prepared the RMA, which was titled “Movement of commercially packed fresh citrus fruit (*Citrus* spp.) from citrus canker (*Xanthomonas axonopodis* pv. *citri*) disease quarantine areas, March 2007.” We made the RMA available for comment along with the proposed rule.⁵ The RMA was also submitted for peer review, which occurred concurrently with the public comment period for the proposed rule.⁶ The RMA analyzed the potential of fresh commercially packed citrus fruit and associated packing material to serve as a pathway for the introduction and spread of citrus canker into new areas. It also identified and evaluated options for regulating the interstate movement of citrus fruit from quarantined areas with the goal of reducing the potential for citrus canker introduction and spread. The recommendations in the RMA served as the basis for the proposed rule.

To develop the RMA, we reviewed available evidence regarding the biology and epidemiology of *Xac* and the management of citrus canker disease. The RMA concluded that the introduction and spread of *Xac* into other commercial citrus-producing States through the movement of commercially packed fresh citrus fruit from quarantined areas is unlikely because:

- Fresh citrus fruit is produced and harvested using techniques that reduce the prevalence of *Xac*-infected fruit;
- Citrus fruit is commercially packed using techniques that reduce the prevalence of infected or contaminated fruit, including disinfectant treatment for epiphytic contamination;
- For a successful *Xac* infection that results in disease outbreaks to occur, an unlikely sequence of events would have to occur;
- Reports of citrus canker disease outbreaks linked to fresh fruit are absent; and

- Large quantities of fresh citrus fruit shipped from regions with *Xac* have not resulted in any known outbreaks of citrus canker disease.

Nevertheless, the RMA concluded that the evidence is not currently sufficient to support a determination that fresh citrus fruit produced in a *Xac*-infested grove cannot serve as a pathway for the introduction of *Xac* into new areas. Therefore, the RMA evaluated several packinghouse-centered risk management options for the interstate movement of fresh commercially packed citrus fruit from regions infested with citrus canker to regions without the disease. These packinghouse-centered risk management options were evaluated to determine whether they provide an appropriate level of phytosanitary protection without the resource constraints and other practical considerations that make it difficult to maintain the grove-centered regulatory approach in Florida. The risk management options evaluated were:

- *Option 1:* Allow unrestricted distribution of all types and varieties of commercially packed citrus fruit to all U.S. States.
- *Option 2:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, subject to packinghouse treatment with APHIS-approved disinfectant and APHIS inspection of finished fruit that has completed the packinghouse culling, washing, disinfection, and grading processes.
- *Option 3:* Allow distribution of all types and varieties of commercially packed citrus fruit (except tangerines) in U.S. States except commercial citrus-producing States. Allow distribution of commercially packed tangerines to all U.S. States, including commercial citrus-producing States. Require packinghouse treatment of all such citrus fruit with APHIS-approved disinfectant and APHIS inspection of finished fruit (all types and varieties) for citrus canker disease symptoms.
- *Option 4:* Allow distribution of all types and varieties of commercially packed citrus fruit in U.S. States except commercial citrus-producing States and require packinghouse treatment of citrus fruit with APHIS-approved disinfectant and APHIS inspection of finished fruit (all types and varieties) for citrus canker disease symptoms.
- *Option 5:* Leave the current regulations for the interstate movement of citrus fruit from citrus canker quarantined areas in place and unchanged.

We proposed to implement Option 4. This option would have limited

distribution of all types and varieties of citrus fruit to States other than commercial citrus-producing States, with mitigations conducted at packinghouses operating under compliance agreements. Those mitigations are the use of an approved disinfectant for all fruit and APHIS phytosanitary inspection.

We received several comments on the overall level of risk associated with the movement of commercially packed citrus from a citrus canker quarantined area, as well as our selection of Option 4. These comments have not led us to change our determination that Option 4 is the most appropriate option to implement. The RMA that we are making available with this final rule contains revisions based on the comments we received on the proposed rule and the comments we received through the peer review process, but its overall conclusion is the same. Accordingly, this final rule implements Option 4. (We are making some changes to the regulatory requirements associated with the implementation of Option 4. These changes are discussed later in this document.)

Some commenters believed that the evidence presented in the RMA warranted the selection of Option 2, which would have allowed the distribution of citrus fruit to all States, subject to packinghouse treatment with APHIS-approved disinfectant and APHIS inspection of finished fruit. These commenters stated that it was extremely unlikely that the circumstances necessary for the movement of commercially packed fresh citrus fruit to result in the introduction and spread of *Xac* into other commercial citrus-producing States would ever occur.

One commenter stated that the decision to allow the movement of regulated fruit from a citrus canker quarantined area only into States other than commercial citrus-producing States, rather than into all States, was based on politics rather than on science.

One commenter stated that no Florida citrus fruit infected with citrus canker has ever been found in a commercial citrus-producing State under the current regulations and that, at the commenter's packinghouse, not a single piece of fruit with citrus canker had been found by any inspectors or employees during the last growing season.

One commenter noted more generally that citrus canker has not been found outside Florida since the disease was first detected there, and stated that more certainty than uncertainty exists regarding the risk of commercially

⁵ The RMA is 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.

⁶ The peer review materials for the RMA may be viewed at http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml.

packed citrus fruit as a viable pathway for citrus canker.

Another commenter noted that the PRA stated the following in its executive summary: "The combination of conditions necessary for introduction are so difficult to achieve that the likelihood of such occurrence is greater than the baseline exposure represented by unregulated pathways. The conclusions of the evaluation are reinforced by a strong record of empirical data from experience and interceptions."

We acknowledge the efforts of the Florida citrus industry to put safeguards in place against citrus canker infestation. The proposed rule recognized the effectiveness of those safeguards by providing for the interstate movement to States other than commercial citrus-producing States of any lot of citrus fruit that is commercially packed, treated with APHIS-approved disinfectant, and inspected by APHIS and found to be free of visible canker lesions.

The RMA concludes that commercially packed fresh citrus fruit is an unlikely pathway for the introduction and spread of *Xac* and that a phytosanitary inspection ensures, with high confidence, that few shipped fruit would have symptoms of citrus canker disease. However, the model in Appendix 1 to the RMA indicates the potential for some commercially packed fruit with visible canker lesions to be shipped to commercial citrus-producing States. That potential for such fruit to reach commercial citrus-producing States, coupled with the aforementioned uncertainty regarding fruit as a pathway, led to the determination that the additional mitigation of prohibiting distribution to commercial citrus-producing States was required. If, in the future, evidence is developed to support a determination that commercially packed citrus fruit (both symptomatic and asymptomatic) is not an epidemiologically significant pathway for the introduction and spread of citrus canker, we would undertake rulemaking to amend our regulations accordingly.

Under section 412(a) of the Plant Protection Act (7 U.S.C. 7712(a)), 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. Based on information provided in the PRA and RMA, we have determined that it is not necessary to prohibit the interstate movement of citrus fruit from a quarantined area into

States other than commercial citrus-producing States under the conditions described in the proposed rule. While APHIS has concluded that commercially packed citrus fruit is an unlikely pathway for the introduction and spread of citrus canker, the remaining uncertainty about the level of risk associated with the movement of citrus fruit from a quarantined area has led us to maintain the prohibition on the movement of citrus fruit into commercial citrus-producing States.

One commenter supplied a report that provided initial data demonstrating that transmission of *Xac* from infected fruit placed directly under highly susceptible grapefruit seedlings does not occur.

The research (which can be viewed at <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=APHIS-2007-0022-0053>) is suggestive; when it is completed, it will help better determine whether citrus fruit can serve as a pathway for the introduction of citrus canker to commercial citrus-producing States outside the quarantined area. We encourage interested parties to make research on this issue available to us.

Two commenters stated that APHIS' treatment of the risk associated with citrus canker was inconsistent with its treatment of the risk associated with other plant pests. For example, one of the commenters stated, the evidence is clear that the interstate movement of nursery stock is a pathway for the long-distance spread of *P. ramorum*, but APHIS' regulations continue to allow high-risk nursery stock to move to all States, under specified conditions. The commenter cited APHIS' actions with respect to the light brown apple moth as another example.

The provisions governing the movement of regulated articles for each pest for which APHIS maintains quarantine requirements are the result of separate considerations of the available science and the risk posed by the plant pest in question. We make our determinations of risk based on, among other things, the likelihood that a pest will follow a specific pathway, the economic and environmental value of resources that could be damaged by the pest, and the likelihood of introduction of the pest into an unaffected area. Our choice of regulatory approach is based on, among other things, the likelihood that the mitigations available to us will be sufficient to prevent the introduction or spread of a plant pest. We have determined that the level of protection against the interstate spread of citrus canker that will be provided by the regulations as amended by this final rule is appropriate.

One commenter asked why APHIS allows fruit to be exported from the quarantined area into the citrus-producing areas of Europe, given that we proposed to prohibit the distribution of fruit from quarantined areas into commercial citrus-producing States. Other commenters asked that we allow the interstate movement of fruit from quarantined areas into commercial citrus-producing States under conditions similar to those required by the European Union (EU) for the importation of citrus fruit into the EU.

APHIS certifies U.S. plant products for export according to the conditions set by the importing country for the exportation of those products from the United States. The EU's requirements for the importation of citrus fruit apply to all areas where citrus canker is present, not just in the United States but in other countries whose citrus production areas are affected by citrus canker.

The EU import requirements involve certification of grove freedom from citrus canker and are similar to, but less restrictive than, the requirements that were in the regulations before the publication of this final rule. For reasons discussed in the RMA, we do not consider these requirements to be sufficient to allow the movement of fruit from citrus canker quarantined areas into commercial citrus-producing States at this time. We will continue to review the available science and will update the regulations if necessary.

Two commenters stated that Option 3, which would have allowed the unlimited distribution of tangerines subject to treatment and APHIS inspection, should be implemented. One commenter stated that canker finds have been few and far between, if the disease has been found at all, on some varieties of tangerine. Another stated that mandarin varieties are the least susceptible to citrus canker, and that the commercial citrus-producing States of California and Texas are important markets for producers of this fruit.

Tangerines are generally grouped in the species *Citrus reticulata* and are widely regarded as less susceptible to citrus canker disease than other commercially grown *Citrus* species. But many of the "tangerine" varieties grown in Florida are hybrids of *C. reticulata* with other more susceptible *Citrus* species. Clearly, tangerines in Florida are not immune to citrus canker, as APHIS records indicate that, during the 2005–2006 growing season grove surveys, *Xac* was detected on 274 samples from tangerine, tangor, and tangelo groves. APHIS pest interception data indicate that between 1985 and

2006, *Xac* was intercepted 632 times on *C. reticulata* fruit. The level of susceptibility was expressed as a continuum across “tangerine” varieties rather than as a discrete immunity for all varieties. This creates a regulatory problem when an overlap occurs in the level of susceptibility expressed by, for example, a more susceptible tangerine variety and a more resistant nontangerine citrus variety. Sufficient evidence does not exist to exclude tangerines from regulations applicable to other Florida citrus varieties. We are making no changes to the proposed rule in response to these comments.

Several commenters supported Option 4 but asked APHIS to continue to examine the scientific evidence with a view toward allowing unlimited distribution of fruit moved interstate from areas quarantined for citrus canker at some future time.

We will continue to examine scientific evidence regarding whether commercially packed citrus fruit (both with and without visible canker lesions) is an epidemiologically significant pathway for the introduction and spread of citrus canker. If, in the future, evidence is developed to support a determination that commercially packed citrus fruit is not an epidemiologically significant pathway for the introduction and spread of citrus canker, we would undertake rulemaking to amend our regulations accordingly.

Some commenters proposed other options to allow the movement of fruit from quarantined areas. One commenter stated that fruit from groves that are free of citrus canker and that are 1,500 feet or farther from an affected grove should be allowed to move fruit to commercial citrus-producing States.

It has been our experience in the State of Florida that citrus canker can spread more than 1,500 feet in stormy conditions. We recognize that citrus canker-free areas may exist adjacent to infected areas, but implementing the commenter’s suggestion would require grove certification programs similar to those in place prior to the publication of this final rule. We have determined that certification of fruit for interstate movement at the packinghouse level rather than at the grove level will ensure an appropriate level of phytosanitary security; would be more reliable and less easily circumvented than the preharvest grove survey required by Option 5; would be consistent with the risk associated with citrus canker and commercially packed fruit from Florida; and would be easier and potentially less costly to implement and enforce than a grove-centered system of mitigations.

Some commenters disagreed with our determination that prohibiting the distribution of citrus fruit from a quarantined area into commercial citrus-producing States would be an effective mitigation. Commenters holding this view stated that the illegal movement of citrus fruit harboring citrus canker from a quarantined area to a commercial citrus-producing State may be expected through current commercial channels; they cited the movement of Spanish clementines from Georgia to Florida through retailer distribution when such movement was prohibited as one example of the potential for incorrect distribution. Another commenter cited the discovery of Florida fruit in commercial citrus-producing States as a result of distribution mistakes.

These commenters also stated that the potential for the movement of Florida citrus by tourists and visitors from nearby States into commercial citrus-producing States should also be taken into account, and that excluding shipments to buffer States would reduce the risk that this movement poses to commercial citrus-producing States. One commenter stated that the history of citrus disease movement such as citrus canker and citrus greening into Florida shows the high risk of movement by plant or by fruit from other citrus-growing countries. In these cases the initial infections were in urban areas, but movement to production areas was undetected until an epidemic was finally observed.

One commenter also stated that we had not addressed mail-order shipment or gift-pack movement of citrus from Florida.

These commenters proposed that we limit the distribution of fruit from citrus canker quarantined areas to other States in addition to the commercial citrus-producing States, thus creating a “buffer zone” around the commercial citrus-producing States. The buffer zones proposed by the commenters varied:

- One commenter suggested that only States east of the Mississippi River should be eligible to receive fruit moved interstate from quarantined areas.
- Two commenters suggested that only States in the northern tier of the United States and east of the Mississippi River should be eligible to receive such fruit.
- Two others suggested a buffer zone of all the States surrounding the commercial citrus-producing States.

We do not agree that a buffer zone, such as these commenters suggest, is appropriate or necessary. Due to the geographic separation between Florida and other commercial citrus-producing

States, citrus canker is not likely to spread through natural means (such as through storms) from Florida to a State that is not a commercial citrus-producing State and then to a commercial citrus-producing State. While it is correct that the movement of plants for planting presents a high risk of spreading citrus canker from a quarantined area, the regulations already contain a prohibition on the movement of plants for planting; currently, only calamondin and kumquat plants are allowed to move interstate from the quarantined area, and those plants must be produced under conditions designed to prevent their infection with citrus canker. As mentioned earlier, we have determined that it is unlikely that the movement of commercially packed citrus fruit is an epidemiologically significant pathway for the spread of citrus canker.

The proposed rule included requirements that boxes or other containers of fruit moving interstate from a quarantined area include a limited permit mark as well as the statement indicating that the fruit is not to be distributed into a commercial citrus-producing State. This requirement (which applies to mail-order and gift-pack shipments as well as truck shipments) will help to prevent inadvertent movement of citrus from quarantined areas into a commercial citrus-producing State. To strengthen the protection provided by the limited permit requirement, we are also adding a requirement in this final rule that the limited permit mark and the distribution statement appear on any shipping documents accompanying boxes or other containers in which fruit is moved interstate.

To ensure that regulated parties comply with distribution restrictions, APHIS routinely monitors wholesalers and fresh fruit markets in commercial citrus-producing States and monitors distribution routes that are bound for commercial citrus-producing States to ensure that Florida citrus fruit does not unlawfully enter those States. This monitoring is conducted primarily by APHIS’ Smuggling, Interdiction, and Trade Compliance program.

If we find Florida citrus in a commercial citrus-producing State, we will trace the product back to its distributor and its origin in Florida. We will investigate violations (through APHIS’ Investigative and Enforcement Services) and may seek penalties against any distributor that moves Florida citrus to commercial citrus-producing States. We may seize the prohibited products and destroy them or ensure they are moved from the area of concern. We

will conduct surveillance on other methods of sale such as Internet sales and gift-pack shipments to ensure that the fruit is not advertised as being available for delivery to commercial citrus-producing States. We will also provide outreach to retailers and wholesalers who are moving products to help prevent any inadvertent movement of citrus from a quarantined area into a commercial citrus-producing State.

The packinghouse measures of disinfection and APHIS inspection ensure that even if a given shipment were illegally moved to a commercial citrus-producing State, the shipment would have a low likelihood of containing fruit with the potential to cause an outbreak of citrus canker disease.

As mentioned earlier, the RMA examined four options for allowing the interstate movement of citrus fruit from a citrus canker quarantined area under a packinghouse-centered approach. Of those four options, we determined that Option 4 was most appropriate, based on the available scientific evidence, which indicates that fruit subject to commercial packing, treatment, and APHIS inspection will be unlikely to serve as a pathway for the introduction or spread of citrus canker.

We recognize that individual consumers may move fruit from Florida into States other than commercial citrus-producing States and then subsequently move that fruit into commercial citrus-producing States. However, such movement could have occurred under the regulations in place before the publication of this final rule as well; APHIS does not have the regulatory infrastructure to monitor interstate movement of fruit by individual consumers. Additionally, even with a buffer zone in place, tourists and visitors would often travel across multiple States to reach their destinations, meaning that a buffer zone would not be highly effective at eliminating this consumer movement. For tourists and visitors, as well as for local residents who routinely move between commercial citrus-producing States and other States, the distance between the borders of commercial citrus-producing States and the citrus-producing areas within those States acts as a buffer as well, further decreasing the risk associated with such movement. Finally, the volume of such movement is extremely low when compared with the volume of commercial movement of fruit, making the risk of citrus canker establishment in commercial citrus-producing States through this scenario highly unlikely. These factors, combined with our determination that

the introduction and spread of *Xac* into other commercial citrus-producing States through the movement of commercially packed fresh citrus fruit is unlikely and that the mitigations of treatment and APHIS inspection are highly effective, have led us to determine that a buffer zone to address such movement is unnecessary.

Scientific Evidence Used in the PRA and RMA

We received several general comments on the scientific evidence we used to make our determinations in the PRA and RMA. One commenter stated that the conclusion reached by the RMA is in part based on the lack of evidence that citrus fruit could play a role in the introduction of citrus canker in new areas, but that this lack of evidence is a consequence of the lack of scientific studies and is not based on scientific data; this commenter suggested that we evaluate the risks further using fruit produced subject to the regulations that were in place before the publication of this final rule. Another commenter suggested an extensive list of experimental data that the commenter believed were necessary to prove that the introduction and spread of *Xac* into other commercial citrus-producing States through the interstate movement of commercially packed fresh citrus fruit from a quarantined area is unlikely. One commenter stated that this program, which the commenter characterized as precedent-setting, requires a much more solid foundation of science and process affirmation than has been developed to date. Other commenters stated that not enough of the evidence we used in developing the RMA had been published in peer-reviewed scientific journals and that we had relied too much on preliminary research in making our determinations.

We used the best scientific evidence available to develop the PRA and the RMA, and we have detailed extensively how this evidence supports the conclusions we present in those documents. It is important to note that, based on the available evidence, we did not conclude that commercially packed citrus fruit could not serve as a pathway for the introduction and spread of *Xac*, but rather that it was unlikely that commercially packed citrus fruit serves as an epidemiologically significant pathway. That is why this final rule prohibits the distribution of such fruit to commercial citrus-producing States.

The Plant Protection Act charges us with ensuring that our decisions affecting imports, exports, and interstate movement of plants and plant products that we regulate under the Act are based

on sound science. To fulfill this mission, we use all the scientific evidence that may be brought to bear on an issue, not just studies published in peer-reviewed journals. Observations based on APHIS' experience, survey and pest detection data, and preliminary experimental results can all provide valuable information to inform a regulatory decision, and we have used them in the PRA and RMA when appropriate. Having said that, the vast majority of the sources cited in the PRA and RMA have been peer-reviewed, as have both the PRA and RMA themselves.

Comments on specific studies we cited in the RMA and PRA are discussed later in this document.

The peer review for the RMA was conducted concurrently with the comment period for the proposed rule. One commenter stated that stakeholders should have the opportunity to review the peer reviewers' comments when submitting their own comments on this document.

We appreciate the commenter's concerns. APHIS had already provided for peer review of and public comment on the PRA, which informed the development of the RMA. In accordance with the Office of Management and Budget's bulletin on peer review, we are also making all the materials associated with the peer review, including the peer reviewers' comments, available at http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml. The conclusion of the RMA did not change as a result of the peer review, which was generally favorable.

One commenter included a late comment on the PRA as a reference, stating that APHIS had not made appropriate changes to the PRA based on the comment.

We reviewed the comment that the commenter included when we developed the revised version of the PRA. We addressed all the substantive points raised by that comment in the revised version of the PRA published with the proposed rule. Many of the points raised by that comment had been previously raised in other comments submitted on the PRA during the comment period.

As discussed earlier, the PRA concluded that asymptomatic, commercially produced citrus fruit treated with a surface disinfectant and subject to other mitigations is not epidemiologically significant as a pathway for the introduction and spread of citrus canker. However, in order to apply the conclusions of the PRA, we determined that we needed to extend its application to evaluate methods by

which fruit could be produced, treated, inspected, packaged, and shipped without resulting in the spread of citrus canker to commercial citrus-producing areas. Accordingly, the RMA addresses the risk associated with all commercially packed fruit; the RMA's recommendations have served as the basis for the Secretary's determination that it is not necessary to prohibit the interstate movement of citrus fruit from a quarantined area into States other than commercial citrus-producing States under the conditions described in the proposed rule. Therefore, specifically addressing comments on the PRA is unnecessary for the purposes of this rulemaking.

The Packinghouse-Centered Approach and the Current Regulations

In evaluating the risk associated with asymptomatic fruit, the PRA assumed that the citrus fruit in question was commercially produced under a specific set of pest management measures. The RMA, while recognizing that effective pest management measures for *Xac* are available to private and commercial growers and are normal production practices for many of these growers, does not assume that measures in the grove are mandatory. Instead, the RMA focuses on treatment with an APHIS-approved disinfectant at the packinghouse and APHIS inspection of fruit to be moved interstate. The recommendations in the RMA served as the basis for the proposed rule.

The regulations in place at the time the proposed rule was published required that fruit moved interstate originate in a grove that was found by an inspector to be free of citrus canker no more than 30 days before harvest (with additional requirements for limes), in addition to treatment of vehicles, equipment, and other articles that are used on the grove and treatment of the fruit itself.

Several commenters objected to APHIS moving away from the grove inspection approach and to the fact that we did not propose to require the use of the commercial production practices described in both the PRA and the RMA. These commenters stated that, under the proposed rule, measures such as copper sprays, designation and exclusion of infected trees, field culling of fruit, and packinghouse culling of fruit were all voluntary, and their effectiveness was unknown. The commenters expressed concern that not requiring these measures would increase the risk associated with citrus fruit moved interstate from a quarantined area.

One commenter stated that in other countries such as Argentina that ship fruit to citrus-producing countries in Europe, strict guidelines are followed that include field inspections and the planting of wind breaks between orchards that minimize wind velocity and subsequent dispersal of inoculum. The commenter stated that these countries realize that inspection of "finished" fruit in the packinghouse alone is not enough to guarantee the shipment of disease-free fruit.

One commenter stated that the objective of a rule addressing Florida's situation should be to prevent citrus canker from being introduced into disease-free areas in the United States; such a rule should not be designed with the primary objective of allowing shipments of fresh fruit from canker-affected areas. This commenter stated that the building blocks of premises and assumptions set forth in the proposed rule and the RMA create risk rather than develop protective barriers.

The regulations promulgated in this final rule include protective barriers against the introduction of citrus canker into other citrus-producing areas: Treatment with a surface disinfectant, APHIS inspection, and a prohibition of the movement of citrus fruit from a quarantined area into commercial citrus-producing States. We have determined that these barriers provide an appropriate level of protection with regard to the movement of citrus fruit from areas quarantined for citrus canker.

The grove certification requirement in place prior to the publication of this final rule and the APHIS packinghouse inspection required under this final rule are not dissimilar in their approach to preventing the interstate movement of fruit with visible canker lesions. Under the regulations in place before the publication of this final rule, none of the grove-centered measures cited by the commenters (copper sprays, designation and exclusion of infected trees, and field culling of fruit) were required. Rather, growers were required to demonstrate that their groves were free from citrus canker, on the basis of an inspection. In order to be found free from citrus canker, and thus have fruit from their groves be eligible for the interstate market, growers had incentives to employ the grove-centered measures described in the PRA and RMA and mentioned by the commenters.

Instead of a grove inspection, this final rule requires an inspection of the finished fruit at the packinghouse, which must operate under a compliance agreement and treat fruit with an approved surface disinfectant. Every lot

of fruit must be inspected by an APHIS inspector for visible canker lesions. While growers are not required to practice measures that would reduce the prevalence of citrus canker in their fruit, and packinghouses are not required to perform their own culling process to remove fruit with visible canker lesions, the regulations promulgated in this final rule still provide them with a strong incentive to do so, since lots of fruit that fail APHIS inspection will not be eligible for interstate movement. Additionally, packinghouse culling for blemished fruit of any kind is already a standard business practice, and field management programs that include the use of copper sprays and field sanitation are already available to producers.

The purpose of the APHIS inspection at the packinghouses is to ensure that fruit moved interstate is free of visible canker lesions, and to prohibit the interstate movement of fruit that is not free of those lesions. From each lot of fruit intended for interstate movement, APHIS will inspect a 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. Lots of fruit that fail inspection will not be allowed to enter interstate commerce.

A packinghouse-based inspection can ensure an appropriate level of phytosanitary security and will be easier to implement and enforce than the grove certification system in place before the publication of this final rule. Because it focuses on the end product, a packinghouse-based inspection will be more reliable and less easily circumvented than the preharvest grove survey that has been required in the regulations. A packinghouse-based inspection is also consistent with the risk associated with citrus canker and commercially packed fruit from Florida. In addition, a phytosanitary packinghouse inspection creates a performance standard for packed fruit that allows citrus producers greater flexibility to determine the most efficient and effective means of producing a compliant product.

Our choice of a packinghouse-based APHIS inspection as a means to prevent fruit with visible canker lesions from being moved interstate, rather than requiring specific grove and packinghouse practices to ensure the production of fruit free of visible canker lesions, is consistent with the recommendations of the 1997 Presidential/Congressional Commission on Risk Assessment and Risk Management. The commission recommended that agencies use alternatives to command-and-control

measures that dictate the use of specific technologies, where applicable (CRARM 1997), in order to encourage flexibility in the choice of risk management alternatives.

One commenter characterized the approach of the proposed rule as a control point approach, and stated that in the past APHIS has applied control point approaches only to quarantine treatments that are able to demonstrate a probit 9 level of effectiveness.

The probit 9 standard (99.997 percent mortality) applies to treatments for insect pests such as fruit flies, not to treatment of pathogens. In any case, the probit 9 standard is not applicable for the surface disinfectant treatment and packinghouse-based APHIS inspection that we are requiring. Scientific evidence indicates that both of these measures are highly effective.

One commenter stated that the PRA and RMA appeared to imply that packinghouse studies conducted to date were based upon fruit with known levels of contamination with *Xac*. The commenter asked how the packinghouse inspection process would achieve the results described in the RMA without grove inspections and without the ability to determine the infection pressure. The commenter also asked how the proposed measures can be effective without knowing the magnitude of the hazard, as expressed by the proportion of infected fruit.

Both of the packinghouse measures that we are requiring in this final rule are effective regardless of infection pressure. The surface disinfectant treatments approved by APHIS reduce numbers of *Xac* cells to low or undetectable levels. The APHIS packinghouse-based inspection 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. In other words, if the infection pressure is higher than 0.38 percent of the fruit, it is 95 percent likely that the lot will be rejected from interstate commerce.

Two commenters cited findings of canker symptoms on fruit exported from Argentina and Uruguay to Spain in stating that symptomatic fruit will often pass through the packinghouse process. These commenters stated that the price growers and packers are receiving for citrus is what drives the quality of the citrus shipped, and that with low prices, low-quality fruit, such as those with canker, are more likely to be introduced into distribution channels.

We agree that, in general, price helps to determine the quality of fruit supplied. However, under the regulations established by this final

rule, the fruit will be subject to an additional APHIS inspection separate from any field inspection and culling or packinghouse culling that may occur. Any lot that fails APHIS inspection will not be approved to move for interstate commerce. Given that, if there is a financial advantage to being able to supply fresh citrus to the interstate market, producers and packinghouses in quarantined areas are likely to employ measures and processes that will allow them to supply fruit free of visible canker lesions for APHIS inspection.

Treatments and Surface Contamination With Xac

The regulations require all fruit moved interstate from an area quarantined for citrus canker to be treated in accordance with § 301.75–11(a). This paragraph has included two treatments: Thorough wetting for at least 2 minutes with a solution containing 200 parts per million (ppm) sodium hypochlorite, with the solution maintained at a pH of 6.0 to 7.5; or thorough wetting 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.

One commenter noted that disinfectants are only effective if the active ingredient is not degraded. The commenter gave the example that sodium hypochlorite is degraded by sunlight and organic matter.

We agree with the commenter's point that it is important to ensure that the treatment is conducted properly. APHIS regularly monitors the treatment of fruit to ensure that the disinfectant agent is at the proper concentration and, in the case of sodium hypochlorite, pH, thus ensuring the effectiveness of the treatment. Under this final rule, we will conduct monitoring under conditions specified in the compliance agreements with packinghouses.

In this final rule, we are amending the treatment regulations to require fruit to be treated at a commercial packinghouse whose owner operates under a compliance agreement. Previously, the regulations had required that treatment be performed either in the presence of an inspector or at a facility whose owner operates under a compliance agreement under § 301.75–7(a)(2); this change will reflect the fact that all fruit intended for interstate movement must be treated at a commercial packinghouse under this final rule.

Several commenters stated that these surface disinfectant treatments may not be 100 percent effective, citing various reports that indicated that bacteria could be recovered from citrus fruit that had been treated with sodium hypochlorite or SOPP, including reports by Verdier (2006) and Golmohammadi (2007) and a newspaper article reporting on a lecture by Gottwald in which he presented unpublished preliminary results. With regard to the last of these, two commenters requested that we provide information about the followup studies mentioned in the article.

As stated in the RMA, the surface disinfectant treatments approved by APHIS reduce numbers of *Xac* cells to low or undetectable levels, but do not necessarily provide complete eradication. The evidence cited by the RMA does demonstrate that the treatments allowed under the rule substantially reduce bacterial populations, including *Xac*, found on the surface of citrus fruit to the extent practicable using surface disinfectant treatments currently registered for use in the United States on raw fruits and vegetables.

Recovery of *Xac* from fruit after surface disinfectant treatment does not demonstrate that the treatment is ineffective. Microbial detection or recovery tests simply measure the presence or absence of the organism in a sample and do not enumerate or measure the difference between the pre- and post-treatment bacteria population levels or infectivity. The treatments in the regulations are consistently reported as dramatically reducing *Xac* populations on the surface of fruit, if not eliminating them entirely. For example, Verdier (2006), cited by the commenters, measured the pre- and post-treatment levels in the wash solution and found that the bacteria population level was reduced 99.8 percent from an average of 39.4 colony-forming units (cfu)/mL on untreated controls to an average of 0.06 cfu/mL on treated fruit.

The information from Gottwald (2006) the commenters cite has not been published, and the followup studies referred to in news reports are currently being completed. We are not able to obtain the unpublished data that have been collected to this point. We will review the Gottwald information when it becomes available in final form. It is important to note again that the recovery of some bacteria after treatment is not inconsistent with treatment being highly effective at reducing *Xac* population levels, as described earlier.

Another commenter, referring to a study by Brown and Schubert (1987)

that the RMA cited, stated that the study's use of *Xanthomonas campestris* pv. *vesicatoria* as a proxy for *X. axonopodis* pv. *citri* in assessing the efficacy of SOPP was not appropriate, because the behavior of closely related bacteria may be very different.

The use of a proxy in efficacy testing is not unusual; for example, the Environmental Protection Agency (EPA) requirements for testing the efficacy of disinfectants allow the use of a proxy. A proxy organism was used in this study because the study was conducted in a model packinghouse. It is difficult to experiment with quarantine plant pathogens in the field because of the need to provide safeguards against their spread. While the bacteria in question are not identical, SOPP has a broad range of efficacy; there is no reason to believe that some feature of *Xac* would defeat the mechanism of SOPP. In addition, the RMA cited other studies establishing the efficacy of SOPP as a treatment against *Xac* itself.

The PRA contained the following statement regarding treatment effectiveness: "Studies performed in Argentina on the effectiveness of sodium hypochlorite on mature symptomless fruit artificially contaminated with *Xac* showed that sodium hypochlorite levels as low as 8 ppm were effective in eliminating epiphytic or surface bacteria from the fruit (Canteros, undated)." One commenter stated that there were no references about the viability of the bacteria, which is an important factor for risk assessment.

This particular study was one of many studies cited in the PRA and RMA establishing the effectiveness of sodium hypochlorite as a treatment. Other studies we cited included references about the viability of the bacteria.

Related to the presence of bacteria on the surface of treated fruit (also referred to as epiphytic bacteria or contamination), several commenters stated that fruit with such populations pose a risk of spreading citrus canker that was not addressed by the measures recommended in the RMA.

While surface populations of *Xac* undoubtedly exist on some citrus fruit that is packed in a quarantined area, and commenters cited scientific evidence establishing this point, substantial evidence indicates that surface bacterial populations do not infect mature fruit or survive on mature fruit long enough to infect other hosts. The evidence cited in the RMA regarding epiphytic survival indicates that epiphytic populations on harvested, mature fruit decline rapidly. For example, researchers in Brazil sprayed asymptomatic fruit, picked

from trees, with a bacterial suspension of 10^6 cfu/mL; no bacteria were recovered after 5 days at room temperature under laboratory conditions (Belasque and Rodriguez Neto 2000). Epiphytic bacteria do not multiply in water on leaf surfaces or on dry leaves (Timmer *et al.* 1996). Graham *et al.* (2000) found that *Xac* survived for 48 to 72 hours on a variety of inanimate surfaces in sun or shade, respectively. Additionally, there is no authenticated record of movement of diseased fruit as the origin for a citrus canker disease outbreak, which is especially suggestive given the brisk global trade in such fruit and the likely presence of some level of epiphytic bacteria on many fruit that is exported from citrus canker-affected areas.

Commenting on the PRA, one commenter noted that a low concentration of 8 cfu/mL (cited as a result of treatment by one study) may mean very high numbers of bacteria in tons of fruit.

The commenter's assertion is correct. However, shipments of fruit are commercially packed in boxes or other approved containers and are dispersed through market channels all over the United States, greatly diluting the concentration of bacteria which are at the same time experiencing rapid mortality. Therefore, such bacterial concentrations would not occur in the real world. In any case, for the reasons stated above, we have determined that fruit with epiphytic bacterial populations is not an epidemiologically significant pathway for the spread of citrus canker.

Some commenters were also concerned about the possible presence of *Xac* on other materials, citing reports of *Xac* survival for various periods on media like clean microscopic slides; leaf surfaces, plastic, wood, and other materials; cloth, sawdust and shavings, dried herbarium tissue, and sterile soil; and non-host weeds.

While *Xac* undoubtedly persists on a number of surfaces, it does not multiply outside of hosts. Under the regulations, the interstate movement of any regulated article other than fruit, calamondin and kumquat plants, and seed is prohibited. Regulated articles include leaves and grass clippings. In addition, under paragraph (c) of § 301.75–3, an inspector may designate any other product, article, or means of conveyance, of any character whatsoever as a regulated article when it is determined by an inspector that it presents a risk of spread of citrus canker and the person in possession thereof has actual notice that the product, article, or means of conveyance is subject to the

provisions of this subpart. We do not typically regulate the movement of the other articles cited by the commenters under the current regulations because populations of *Xac* on such articles are very unlikely to infect mature citrus fruit.

Two commenters were concerned about the possibility that canker-infected fruit could contaminate packinghouse equipment with *Xac*. One commenter stated that packinghouse equipment needs to be disinfected if citrus canker is found in a lot run on that equipment. The other expressed a specific concern about contamination of existing wounds in fruit and stated that surface disinfestation cannot be continuously done during the commercial packing of fruit where both diseased and healthy fruit are being packed. This commenter suggested that we amend the regulations to exclude fruit from being packed from orchards or harvested fruit lots with an incidence of citrus canker above some established threshold, in order to minimize contamination of packing lines.

We acknowledge that infected fruit in a lot could contaminate the packing line with *Xac*, but, as stated above, substantial evidence indicates that the epiphytic bacterial populations that could be transferred from the packing line to the fruit do not infect mature fruit or survive on mature fruit long enough to infect other hosts. For that reason, we have determined that grove inspections are not necessary to mitigate the risk associated with such contamination, nor is disinfection of the packing line equipment necessary if canker is found during the inspection of a lot of fruit.

The RMA stated that "Bacteria within lesions may be more protected from the detrimental effects of washing, disinfection and drying. Viable *Xac* has been recovered by APHIS pathologists from citrus canker lesions on fruit culled from packinghouse lines after postharvest treatments (Riley 2007)." A few commenters expressed concern relating to this statement. One stated that chlorine is well known as a surface sanitizer but has no ability to penetrate beyond the surface—for example, into lesions. Another commenter noted that none of the experiments mentioned in the PRA or RMA evaluate the effect of disinfectants on *Xac* within the fruit, either in visible lesions (of any size) or in circumstances where the effects of *Xac* are not visible to the naked eye. The third, reacting to the statement about recovery of viable *Xac* by APHIS pathologists after postharvest treatments, asked what treatment had been performed, what level of recovery

had occurred, what preharvest management the fruits were subject to, why the fruits were not culled on the packing line before treatment, and whether the postharvest treatment included wax.

As stated earlier, the surface disinfectant treatments required in this final rule reduce numbers of *Xac* cells to low or undetectable levels. The RMA acknowledges that treatment with surface disinfectants is not effective on canker lesions, which is why this final rule also requires an APHIS inspection of each lot of fruit for canker lesions.

The canker lesions referred to in Riley (2007) occurred in fruit produced under the regulations that were in place before the publication of this final rule, i.e., with certification of grove freedom and with surface disinfectant treatment. As the regulations in place before the publication of this final rule did not require specific canker management measures, we do not have records of what canker management measures the fruit may have been subject to beyond the measures required by the regulations.

Addition of Peroxyacetic Acid Treatment

We proposed to add a new surface disinfectant treatment using peroxyacetic acid (PAA). The proposed rule would have required the regulated fruit to be thoroughly wetted for at least 1 minute with a solution containing 85 ppm peroxyacetic acid. At the request of growers in Florida, we evaluated the efficacy of this treatment and determined that the disinfectant is at least as efficacious as a surface disinfectant treatment as the currently approved disinfectants listed in the regulations. In the RMA, we described the tests that had been performed to confirm the efficacy of PAA. These tests were conducted on *X. axonopodis* pv. *citrumelo* (*Xa citrumelo*), which was used as a surrogate for *X. axonopodis* pv. *citri* (i.e., *Xac*).

Two commenters stated that PAA should be tested on *Xac* itself rather than on a surrogate. One stated that *Xa citrumelo* does not infect fruit and does not survive in orchards, making it a poor surrogate, and asked that we make the data referred to in the RMA publicly available. Another stated that, while it seems highly likely that PAA may be effective against *Xac*, to allow its use without any testing against the particular organism of concern appears to be unnecessarily optimistic. The commenter recommended testing in field conditions for this application or at least to demand post-introduction

testing to demonstrate efficacy in the field.

We are making the data on PAA testing available on the Regulations.gov Web site with this final rule (see footnote 1 at the beginning of this final rule) or from the person listed under **FOR FURTHER INFORMATION CONTACT**.

As noted earlier in this document, the use of a proxy or surrogate is not unusual when testing a treatment's efficacy on a quarantine pathogen. The EPA label for PAA, which states the approved instructions for use and applicability of the disinfectant, acknowledges that it was tested on *Xa citrumelo* as a surrogate for *Xac*.

X. axonopodis pv. *citrumelo* and *X. axonopodis* pv. *citri* differ primarily in the hosts they infect. ("pv." stands for "pathovar," which distinguishes strains or subspecies of the same bacteria based on their ability to only infect specific hosts.) *X. axonopodis* pv. *citrumelo* is generally considered to be more resistant to disinfection than *X. axonopodis* pv. *citri*, making the former a suitable surrogate for the latter.

In addition, PAA is an oxidizing agent whose mode of action has been shown to be effective on many bacteria, including *Bacillus cereus*, *B. subtilis*, *B. stearothermophilus*, *Clostridium botulinum*, *C. butyricum*, *C. sporogenes*, *Ditylenchus dipsaci*, *Enterococcus faecium*, *Escherichia coli* (including *E. coli* O157:H7), *Fusarium oxysporum*, *Gluconobacter oxydans*, *Lactobacillus plantarum*, *L. thermophilus*, *Leuconostoc mesenteroides*, *Listeria monocytogenes*, *Pseudomonas aeruginosa*, *P. fluorescens*, *Saccharomyces cerevisiae*, *Salmonella typhimurium*, *Staphylococcus aureus*, *Streptococcus delbreuckii* subsp. *bulgaricus*, and *Yersinia enterocolitica*. Based on PAA's characteristics as a general disinfectant and the results of the testing on *Xa citrumelo*, we have determined that PAA will be effective on *Xac* as well, and we are adding PAA as a surface disinfectant treatment for fruit in this final rule.

We are making three other changes related to PAA. While paragraph (a) of § 301.75–11 sets out treatments for fruit, paragraph (d) of that section sets out requirements for treatment of vehicles, equipment, and other articles. A solution of 85 ppm of PAA is also effective when used on vehicles, equipment, and other articles, and the availability of PAA as a treatment for packing line equipment would be useful for packinghouses in the quarantined area to fulfill the requirements in § 301.75–7(c)(2)(iv) for disinfection of packing equipment between packing lots of regulated fruit produced in a

quarantined area and packing lots of fruit not produced in a quarantined area. Therefore, this final rule also adds PAA, when used indoors, as an approved treatment for vehicles, equipment, and other articles in paragraph (d) of § 301.75–11. We may decide to add PAA as a treatment for outdoor use in a separate rulemaking if we receive requests to do so.

The proposed rule would have added PAA as a fruit treatment in a new paragraph (a)(4) in § 301.75–11. Paragraphs (a)(1) and (a)(2) authorize the use of sodium hypochlorite and SOPP, respectively, as treatments for fruit; paragraph (a)(3) requires that these two surface disinfectants be applied in accordance with label directions. Instead of adding PAA in a new paragraph (a)(4), we have redesignated paragraph (a)(3) as (a)(4), added PAA in paragraph (a)(3), and amended paragraph (a)(4) to indicate that PAA must be applied in accordance with label directions as well.

The regulations in 7 CFR part 305 set out the requirements for phytosanitary treatments. Section 305.11 contains the two treatments that have been authorized for citrus fruit moved from a citrus canker quarantined area. Accordingly, in this final rule, we are amending that section to add PAA as a treatment for fruit.

Inspection and Potential for Mature Fruit Without Visible Lesions To Serve as Pathway for Infection

As mentioned earlier in this document, the PRA examined the risks associated with asymptomatic fruit. The PRA used the term "asymptomatic" to refer to the lack of visible signs or symptoms of citrus canker. The RMA examined the risks associated with all fruit that has been commercially packed, regardless of its disease status. We also prepared a quantitative model (Appendix 1 to the RMA) based on Florida production and shipping data to evaluate the efficacy of three levels of phytosanitary inspection in ensuring that symptomatic fruit does not enter commercial citrus-producing States. In the qualitative model, we defined "symptomatic" as meaning that the fruit have visible *Xac* lesions 1 millimeter (mm) in diameter and greater. One commenter pointed out that these terms were used inconsistently in the PRA and the RMA.

We appreciate the comment. In the version of the RMA that accompanies this final rule, Appendix 1 refers to fruit that have visible canker lesions and fruit that do not, rather than to symptomatic and asymptomatic fruit.

This commenter further stated that the proposed APHIS inspections of fruit target only relatively large symptoms readily visible to the naked eye, not whether any bacteria are present on the fruit. While the APHIS inspection is probably fairly effective at limiting the occurrence of larger *Xac* lesions in marketed fruit, the commenter stated, inspection is totally ineffective at detecting and limiting lesions smaller than 1 mm or at detecting *Xac*-infected fruit that have no visible lesions at the time of inspection. This commenter and other commenters also addressed surface populations of bacteria, stating that focusing inspection efforts on visible lesions ignores risk associated with bacteria.

We addressed the risk associated with epiphytic bacterial populations earlier in this document. We have determined that the other situations described by these commenters are unlikely to occur outside of an experimental setting. The reasoning behind this determination is discussed below.

Small lesions (less than 1 mm).

Commenters cited Koizumi (1972), in which Satsuma mandarin were either prick inoculated with *Xac* or naturally infected. The experimenter found that, in addition to lesions greater than 1 mm, lesions referred to as "late detection (small)" of a size of 0.1 to 0.15 mm also occurred. This would be below what we have determined to be the size threshold for a detectable lesion, as defined in Appendix 1 to the RMA. Besides stating that the existence of such lesions indicates that fresh fruit could be a pathway for the introduction or spread of citrus canker, the commenter also stated that it is possible that disinfecting the surface of the fruit might exacerbate the subsequent infectivity of *Xac* exuding from small lesions, by removing other (e.g., rot-provoking) organisms that might directly or indirectly accelerate the decline of *Xac* after harvesting.

As discussed in the RMA, in the field, immature citrus is most susceptible to infection with *Xac* and lesion development. Mature citrus fruit have natural wax layers on their surface, decreasing susceptibility by reducing access to natural openings, such as stomata. In addition, mature (not expanding) asymptomatic fruit without injuries or blemishes are not known to develop symptoms in the field. In the Koizumi (1972) study, mature fruit were experimentally inoculated while the fruit was still attached to the tree; equivalent conditions are extremely unlikely to occur naturally.

The lesions Koizumi observed resulted from a combination of artificial

(prick) inoculations and natural infections and therefore provide little information about how the ratio of typical to atypical lesions on fruit varies under natural conditions. Koizumi's results varied greatly over the several years he conducted these experiments; the commenters cite results from the year with the highest incidence of infection, which coincided with unusually high temperatures and two typhoons (hurricanes). Koizumi speculated that the atypical lesions were the result of restricted expansion brought on by physiological changes in the maturing fruit and lower ambient temperatures. As noted by Graham *et al.* (1992b), the small late season lesions were characterized by a "lack of bacterial proliferation." Lesions without proliferation would not provide an epidemiologically significant source of inoculum for *Xac* infections.

While other studies have conducted similar inoculation tests on fruit before (Fulton and Bowman 1929) and after (Graham *et al.* 1992b; Verniere *et al.* 2003), Koizumi (1972) remains the only paper to describe this type of lesion. Fulton and Bowman noted that if one was not careful to avoid oil glands when making puncture inoculations, the released oils cause injuries to the adjacent tissue. One could speculate that at least some of Koizumi's atypical lesions might, in fact, be injuries. We have no evidence that the lesions described by Koizumi (1972) occur in nature and therefore cannot agree that they would occur at the rates cited by the commenters.

Nevertheless, conditions could exist in which small *Xac* lesions occur. However, as noted above, immature fruit are most susceptible to *Xac* infection, and *Xac* lesions grow as the fruit matures; the growth of the lesions slows as the fruit reaches maturity. Picking mature fruit from the tree causes senescence of the fruit and further inhibits lesion development. Therefore, while small lesions might occur on immature fruit, they would typically grow into larger lesions as the fruit matures; if there were small lesions present on such fruit, it would be likely that lesions larger than 1 mm would be present as well. In general, APHIS inspectors do not see fruit with only lesions smaller than 1 mm; small lesions occur in association with larger lesions (Riley 2007).

The packinghouse culling and grading procedures are designed to remove fruit with visible lesions and would result in removal of the fruits likely to harbor the highest pathogen loads, and therefore present the greatest risk of disease transmission. The APHIS inspection

after the packing process is completed will result in the rejection of any lot of fruit that has visible canker lesions and will prevent that lot from moving in interstate commerce.

Wounded fruit. One commenter cited Fulton and Bowman (1929), who inoculated a mature grapefruit from the market and 75 days later tested the grapefruit. The test indicated that there were "something like 32,000 bacteria per puncture," although the fruit had not developed external lesions. Another commenter stated that a general principle of postharvest pathology is that surface disinfestation of fruit with standard oxidizing chlorine washes will inactivate most microorganisms from the surface of non-wounded fruit, but not from fruit wounds.

The grapefruit described in Fulton and Bowman (1929) was one of a number of market fruit that were inoculated in this way, the rest of which either rotted after inoculation or supported bacterial populations that did not multiply. All these fruits were kept in moist laboratory conditions designed to facilitate the development of *Xac* bacteria.

Regarding the grapefruit, Fulton and Bowman stated the following in their 1929 study: "There is apparently a very marked difference in the behavior of the canker organism following inoculations in the peel of mature fruit after removal from the tree as compared with its behavior in the peel of mature fruit still on the tree. Possibly changes in the physiological condition of the fruit resulting from its removal from the tree are responsible for the difference * * * senescent changes in the peel favor the development of fungi having saprophytic tendencies; it is not inconsistent to presume these changes would in equal degree hinder the development of an organism having definitely parasitic habits like *Pseudomonas citri* [*Xac*]." This is consistent with a determination that infected wounds would occur extremely rarely in real-world conditions.

Fulton and Bowman also reported that infection only occurred if the wound stayed moist until the time of inoculation. Wounds that were allowed to dry and were inoculated after 26 hours did not result in infection. That is, infections occurred only when oil glands were avoided and inoculum was applied within 26 hours of wounding (Fulton and Bowman 1929). Verniere *et al.* (2003) reported a disease incidence of zero when inoculating mature fruit either by pin prick or spray inoculation.

As noted above, the conditions that would allow citrus canker to develop in wounds in the field are unlikely to

occur. In addition, any fruit with wounds would likely be culled in the field or by the packinghouse before it could be submitted for APHIS inspection.

Based on this evidence, we have determined that fruit with small lesions or infected wounds would occur extremely rarely and are not likely to be epidemiologically significant when they do appear. Therefore, it is appropriate to focus our inspection efforts on detecting lesions 1 mm or greater.

The RMA stated that APHIS plant pathologists have intercepted fruit in final packed cartons with lesions in the 2–3 mm range and have observed that the majority of the symptomatic fruit that APHIS inspectors intercepted after passing through the packing line undetected by graders have only one lesion (Riley 2007). Two commenters addressed this statement. Both asked for data on interceptions in Florida fruit, with one asking for information on how many fruit were detected and what varieties were found to be infected.

These data are available from the person listed under **FOR FURTHER INFORMATION CONTACT**.

One commenter stated that the fact that APHIS inspectors intercepted fruit with lesions did not substantiate the statement made later in the RMA that grading and inspection procedures are effective in removing fruit with visible lesions. Another commenter stated that all canker infections cannot be detected in packinghouses without knowing whether the fruit originates from a canker-free grove, or at least a grove with a very low level of canker infection. The commenter stated that it is very difficult, if not impossible, to distinguish canker blemishes from numerous other blemishes, especially in the growing conditions that prevail in Florida, where many blemishes appear on fruit.

One commenter cited the example of citrus affected by septoria, a fungus, that are exported to Korea. This commenter stated that the California citrus industry conducts vigorous training programs for line employees to identify and eliminate fruit with distinguishable symptoms and that this culling is then augmented by laboratory analysis. The commenter stated that lab analysis has always detected symptoms on a small percentage of fruit missed by highly trained employees.

We appreciate the opportunity to clarify this point. Various evidence, as cited in the RMA, indicates that packinghouse grading and inspection procedures are effective in removing fruit with visible lesions. Packinghouse graders and inspectors in Florida also

receive training provided by the State in identifying canker lesions. The phytosanitary inspection that will be performed by APHIS in this final rule will provide another layer of inspection protection. We provided evidence supporting these points in the RMA, including detailed evidence about the efficacy of APHIS' inspection process. Scientific evidence indicates that these measures are highly effective, but since uncertainty remains about the epidemiological significance of symptomatic fruit, we are prohibiting the distribution of fruit moved interstate to commercial citrus-producing States.

As discussed earlier in this document, the APHIS packinghouse-based inspection 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. In other words, if the infection pressure is higher than 0.38 percent of the fruit, it is extremely likely that the lot will be rejected from interstate commerce. APHIS inspection is thus effective regardless of infection pressure.

One commenter, responding to both the evidence presented for APHIS inspectors' detection efficacy in the qualitative portion of the RMA and in the model in Appendix 1, stated that none of the evidence provided for APHIS inspectors' detection efficacy corresponds to field conditions for detection of lesions. The commenter noted that the cited figures for refresher training correspond to identification within 40 seconds of a lesion presented to the inspector, which the commenter stated was inconsistent with location of a rare lesion on a fruit in a continuous search of 1,000 fruit samples within an average of 5 seconds, an estimate we presented in the Regulatory Impact Analysis for the proposed rule in the context of describing the proposal's potential impact on packinghouse operations. The commenter stated that evaluation of enzyme-linked immunosorbent assay (ELISA) Dip Stick tools and the evaluation of a diagnostic tool (if that is a separate exercise from the ELISA Dip Stick tool) also corresponded to classification of already-detected lesions.

We appreciate the opportunity to clarify the evidence presented in the RMA on the APHIS phytosanitary inspection. The evidence provided in the RMA is consistent with the proposed rule's approach of using inspection to detect lesions in the packinghouse. The training for phytosanitary inspectors was done in packinghouse conditions, using culled fruit for the test sample. Both in training and testing and in the packinghouse,

inspection is performed on fruit that has been removed from the packing line.

Under packinghouse conditions, there is no time limit for fruit inspection once the fruit is randomly sampled. This can be accomplished because the fruit is inspected individually, away from the packing line. The 40-second time limit during training is a performance requirement for training, not a packinghouse inspection requirement. The estimate that the packinghouse inspection would require 5 seconds per fruit is also not an APHIS packinghouse inspection requirement; rather, this figure was cited in the context of the potential economic impact of the lot inspection on the packinghouse, and specifically in discussing possible delays associated with inspection. Inspectors who see questionable lesions will be able to take whatever time is necessary to determine whether those lesions are canker lesions.

The ELISA Dip Stick test did correspond to already detected lesions. The results of the ELISA Dip Stick test were cited in the RMA to provide empirical data on the size of lesions that can be detected by inspectors. The ELISA Dip Stick test is not part of the detection system that will be used in commercial packinghouses under this final rule; it will be used only for confirmation of lesions found by inspectors.

One commenter disagreed with the idea that only "finished" fruit would be inspected for citrus canker in the packinghouse. The commenter stated that citrus canker is more easily detected on fruit that has not been through the packing process. Brushing of fruit on the packing line may remove diseased tissue, the commenter stated, and waxing of the fruit will make the disease harder to diagnose.

Inspection of fruit before they go through the packing process would not allow the packinghouses themselves to cull canker-infected fruit prior to packing. In the RMA, we described in detail the efficacy of inspection of finished fruit for citrus canker, as discussed earlier.

Our experience indicates that washing fruit will make it easier to detect citrus canker lesions. Citrus fruit that comes directly from the field is often covered in dirt, sooty mold, and other debris and material that could obscure citrus canker lesions. Washing the fruit removes some of this material. Because citrus canker lesions occur within the peel of the fruit, they would not be brushed off during finishing. Additionally, the wax used on fruit is transparent, which means it would not impede disease detection.

Potential Pathways for Spread of Citrus Canker Through Movement of Fruit

As mentioned earlier, the RMA that was made available with the proposed rule concluded that the introduction and spread of *Xac* into other commercial citrus-producing States through the movement of commercially packed fresh citrus fruit is unlikely because:

- Fresh citrus fruit is produced and harvested using techniques that reduce the prevalence of *Xac*-infected fruit;
- Citrus fruit is commercially packed using techniques that reduce the prevalence of infected or contaminated fruit, including disinfectant treatment for epiphytic contamination;
- For a successful *Xac* infection that results in disease outbreaks to occur an unlikely sequence of events would have to occur;
- Reports of citrus canker disease outbreaks linked to fresh fruit are absent; and
- Large quantities of fresh citrus fruit shipped from regions with *Xac* have not resulted in any known outbreaks of citrus canker disease.

One commenter stated that we did not enumerate any complete pathways for transmission and so did not evaluate the scientific evidence in such a way as to evaluate the possibility or likelihood for transmission along such pathways. The commenter also stated that there are pathways (including illegal diversion of fruit and perfectly legal amateur grower activities) from every part of the country that may lead to infection of commercial citrus areas and that have not been evaluated. This commenter and another commenter suggested several potential pathways that we had not addressed in the RMA.

In general, it is difficult to examine quantitatively the pathways by which infected fruit could theoretically spread citrus canker. Those pathways are dependent on consumer behaviors and biological events for which we lack data that we could use to quantify them, and no such data were provided by the commenters. This lack of data is one reason we have determined that it is appropriate to prohibit distribution of fruit moved interstate from a quarantined area to commercial citrus-producing States. As discussed earlier, such a prohibition, combined with the monitoring and enforcement efforts APHIS will use to ensure that the prohibition is adhered to, is effective at preventing the illegal movement of fruit.

We discuss the specific pathways brought up by the commenters below.

One commenter suggested that citrus canker could be spread through long-

distance movement due to storm or cyclone activity.

The available evidence indicates that the maximum range for spread of citrus canker through storm activity would not be sufficient to spread citrus canker from Florida to another commercial citrus-producing State.

One commenter suggested that citrus canker could be spread through movement on workers' clothes and picking bags.

As discussed earlier, while *Xac* can persist on a number of surfaces, its infectivity outside lesions is unknown. We do not agree that it is likely that workers will move between Florida and other commercial citrus-producing States without laundering their clothes and while carrying their own picking bags. The commenter provides no evidence that could be used to empirically estimate the frequency of such behavior, and APHIS is unaware of any such evidence.

Two commenters suggested that citrus canker could be spread if fruit or peel from citrus fruit infected with *Xac* is placed in or around susceptible host plants, after which a water event moves the bacterium from the fruit or peel to the host plant. One commenter cited Koizumi (1972) as evidence that *Xac* could be recovered from fruit peel for months if the peel was placed in physiological solution for 2 hours. This commenter stated that only one bacterium is required to cause infection. Another commenter cited fruit with live *Xac* cells that are thrown into a compost pile or bin under a backyard citrus tree, after which a splash or water movement occurs. Once a backyard citrus plant was infected, these commenters stated, rain or storm events could spread the bacterium to commercial citrus groves.

The Koizumi (1972) study recovered bacteria using physiological solution, a buffered saline solution that ensures optimal conditions for bacterial recovery. Analogous conditions do not occur in nature. Additionally, for this scenario to occur, citrus fruit that is infected would have to have been moved from a quarantined area into a commercial citrus-producing State—movement that is prohibited by the regulations. As discussed earlier, we are increasing monitoring and disease surveillance activities and making changes to the regulations in order to help prevent the illegal or inadvertent movement of fruit from quarantined areas into commercial citrus-producing States. If an infected fruit was illegally moved into a commercial citrus-producing State, it would have to be exposed to susceptible plants under very specific physical and

environmental conditions for infection to occur.

While it is true that one bacterium is sufficient to cause infection, that one bacterium would have to encounter conditions that were appropriate for infection. There is a very low likelihood that any one bacterium will encounter conditions sufficient to cause infection; it is difficult to create these conditions even in a laboratory setting. Under natural conditions, it would require thousands if not millions of tries for one bacterium to cause infection. Gottwald and Graham (1992) estimated that as few as 2.4 *Xac* bacteria forced into a water congested stomatal cavity of a susceptible plant were sufficient to cause a lesion. However, they also determined that the minimum concentration of bacteria in the inoculum needed to produce an infection, and presumably to place the estimated 2.4 bacteria in a stomatal cavity, was 10^5 cfu/mL. Thus, although it may take only 2.4 infective bacteria in the right place to cause infection, it takes exponentially greater numbers of bacteria in the inoculum for those 2.4 bacteria to occur in the right place at the right time.

The data submitted by one commenter (see <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=APHIS-2007-0022-0053>), in which infected fruit were placed next to grapefruit seedlings in natural conditions for 2 months without infection of the seedlings, suggests that the likelihood of such an occurrence may be low.

Finally, for this pathway to occur, rain or storm conditions would have to prevail that could spread the bacterium over long distances, but Borchert *et al.* (2007) concluded that such conditions are unlikely to prevail outside Florida, the State that is currently quarantined for citrus canker.

We acknowledge that it is possible that all of these circumstances could prevail, but such a "perfect risk" scenario would be an extremely rare event. The commenter provides no evidence that could be used to empirically estimate the frequency of this behavior, and APHIS is unaware of any such evidence.

One commenter suggested a fruit-to-human-to-plant pathway for the introduction of citrus canker into a commercial citrus-producing State. A hobbyist who cultivates citrus in a State other than a commercial citrus-producing State could handle infective citrus from the quarantined area, then infect the plants the hobbyist is cultivating. The hobbyist might not notice the canker infection and could

subsequently move the infected plants into a commercial citrus-producing State.

We acknowledge that such an occurrence is possible, but such a "perfect risk" scenario would be an extremely rare event. The commenter provides no evidence that could be used to empirically estimate the frequency of such amateur citrus grower behavior, and APHIS is unaware of any such evidence.

None of the pathway scenarios suggested by the commenters have changed the RMA's conclusion that an unlikely sequence of epidemiological events would have to occur for a successful *Xac* infection that results in disease outbreaks to occur as a result of the movement of commercially packed, treated, and APHIS-inspected fruit to States other than commercial citrus-producing States.

Potential for Citrus Canker Establishment in Commercial Citrus-Producing Areas

The RMA included a discussion of the susceptibility of commercial citrus-producing areas that are not currently quarantined for citrus canker to the spread of the disease. This discussion included a reference to a study by Borchert *et al.* (2007) that developed a citrus canker spread model using the North Carolina State University APHIS Plant Pest Forecast System to identify areas where citrus canker could become established in the major citrus-producing regions of the United States.

Two commenters stated that modeling of pathogen establishment, infection, and disease severity should be an essential component of the risk assessment for each citrus-producing State and region within the State, adding that the Borchert project results should be made publicly available.

We disagree that modeling of pathogen establishment, infection, and disease severity in commercial citrus-producing States is a necessary component of the risk assessment. The RMA concluded that the introduction and spread of *Xac* into other commercial citrus-producing States through the movement of commercially packed fresh citrus fruit from quarantined areas is unlikely. Nevertheless, because the RMA concluded that the evidence is not currently sufficient to support a determination that fresh citrus fruit produced in a *Xac*-infested grove cannot serve as a pathway for the introduction of *Xac* into new areas, we are prohibiting the interstate movement of fruit from a quarantined area into commercial citrus-producing States.

This measure makes modeling of pathogen establishment, infection, and disease severity in commercial citrus-producing States unnecessary.

The Borchert *et al.* (2007) study is an internal APHIS document. We made the study available to commenters who requested it during the comment period, and it is available from the person listed under **FOR FURTHER INFORMATION CONTACT**. The Borchert *et al.* (2007) study provides the modeling requested by the commenters.

Some commenters addressed the risk citrus canker posed to specific States. One commenter stated that California is a fresh citrus State with more than 200,000 acres dedicated to the fresh market production of oranges, lemons, grapefruit, mandarins, and other citrus varieties. Although the majority of the oranges are grown in arid areas, many of the lemons and some of the grapefruit are produced in climates with higher humidity and rainfall. The commenter stated that the survival of canker in these areas would be expected; the survival of canker in the more arid areas is less certain, but canker's potential impact cannot be ignored based on survival reports from other arid lands. Another commenter, addressing the suitability of California's climate for development of citrus canker, stated that Dalla Pria *et al.* (2006) stated that the greatest severity of canker occurred at 24 hours of leaf wetness, with 4 hours of wetness being the minimum duration sufficient to cause 100 percent incidence at optimal temperatures of 25 °C to 35 °C.

Another commenter stated that when Texas had citrus canker, it was in southeast Texas, which has higher rainfall than the Rio Grande Valley. The Rio Grande Valley generally has high relative humidity, although the commenter stated that there is tremendous variability in Texas' weather patterns; for example, July 2007 has been very wet. The commenter stated that canker would be able to thrive in the conditions present in the commercial growing area of South Texas. Surveys for citrus greening, the commenter stated, have revealed that Texas has substantial amounts of citrus in an area approximately 100 miles north of the Gulf of Mexico from Brownsville to Houston. The commenter noted that the challenges of eradicating canker in the urban areas of Florida contributed to the failure of the eradication program and anticipated that many of those same difficulties would be experienced in Texas if citrus canker appeared in urban areas.

We agree with these commenters that citrus canker could be introduced to

California and Texas. The RMA cited Peltier and Frederick (1926) as indicating that the disease "could develop in all of the citrus regions of the world *sometime* over the growing season." These facts do not change our conclusions that (1) only a small portion of each commercial citrus-producing State actually produces citrus, and an even smaller portion has a climate suitable for canker disease development; and (2) the climate in Florida is the most favorable of any State for the development of citrus canker, and it would be more difficult for citrus canker to be introduced into and subsequently become established in any other State. Regardless, the remaining uncertainty about the level of risk associated with the movement of citrus fruit from a quarantined area has led us to maintain the current prohibition on the movement of citrus fruit into commercial citrus-producing States.

Two commenters urged APHIS to address the risk of spreading citrus canker to other potential host areas, which may not be areas where citrus is commercially produced. One commenter stated that citrus (not just fruit-bearing trees) can be and is grown in other areas of the United States, and those areas are also at risk of citrus canker. The commenter noted that during the initial outbreak of citrus canker in the mainland United States, disease outbreaks were also recorded in Alabama, Mississippi, South Carolina, and Georgia. The commenter also noted that Borchert *et al.* (2007) were tasked "to identify areas where citrus canker could become established in the major citrus producing regions of the United States," rather than all the areas in the United States in which citrus canker could become established.

These commenters recommended that the RMA and the proposed rule take account not only of current commercial citrus-producing areas, but also areas where citrus currently grows (even if it is not commercially grown) and areas where citrus could grow, but does not currently. These commenters stated that establishment of citrus canker in any such area might subsequently lead to establishment in commercial areas, since many of these areas are contiguous with commercial areas, and long-distance transport now appears to be more likely than historically, presumably due to the presence of the Asian leafminer (*Phyllocnistis citrella* Stainton) in Florida. These commenters also stated that citrus canker establishment in areas where citrus is not commercially produced would lead to other pathways for establishment in areas where it is.

The focus of the citrus canker program has been on commercial citrus-producing States because these States present the highest likelihood for introduction of the disease, due to the density of citrus plantings in those States. Prohibiting the movement of fruit from areas quarantined for citrus canker to States other than commercial citrus-producing States would be overly restrictive.

We acknowledge that dooryard plantings of citrus exist outside of commercial citrus-producing States. However, while canker infection in a State other than a commercial citrus-producing State could serve as a pathway for introduction into a commercial citrus-producing State, as discussed earlier under the heading "Potential Pathways for Spread of Citrus Canker Through Movement of Fruit," an unlikely sequence of epidemiological events would have to occur in order for citrus canker to be introduced and established through the movement of citrus fruit from a quarantined area.

If, in the future, commercial quantities of citrus are planted in a State that is not currently designated as a commercial citrus-producing State, we will designate that State as a commercial citrus-producing State in § 301.75–5.

As discussed in the RMA, injuries caused by the Asian leafminer can produce wounds that serve as infection courts in leaves and, to a lesser extent, fruit, but the leafminer itself is not a vector for the spread of citrus canker.

Potential Application of the Packinghouse-Based APHIS Inspection System to Imported Citrus

The regulations in 7 CFR 319.28 prohibit the importation of citrus fruit from areas where citrus canker is present, except for Unshu oranges from Japan and Cheju Island, Republic of Korea, that are produced in accordance with the systems approach described in paragraph (b) of that section. The systems approach for Unshu oranges from Japan and Korea requires measures to ensure that the oranges are produced in an area free from citrus canker; for Unshu oranges from Japan, the systems approach requirements also address the citrus fruit fly.

Several commenters expressed concern that the proposed regulations, if implemented, could lead to requests from other citrus-producing countries to export citrus fruit under conditions similar to those we proposed for the interstate movement of fruit from citrus canker quarantined areas. The commenters noted that, under international trade agreements, APHIS

has agreed not to impose conditions on the importation of commodities that are more restrictive than those we impose on the domestic movement of similar commodities. These commenters stated that the RMA should consider the risk associated not only with the interstate movement of citrus fruit from domestic quarantined areas but also the risk associated with potential imports from foreign citrus-producing areas affected with citrus canker.

One commenter who had expressed concern about illegal movement of Florida citrus into commercial citrus-producing States stated that this potential problem would only increase if citrus fruit was allowed to be imported from foreign areas affected with citrus canker.

Our analysis of the risk associated with the importation of citrus fruit from other countries where citrus canker exists under conditions similar to those in this final rule would be conducted separately from the analysis we conducted for this rulemaking. Before we would consider using an approach similar to that promulgated in this final rule to allow the importation of citrus fruit from canker-affected areas in another country, 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 and phytosanitary inspections; it would also be required to have a bilateral workplan in place with APHIS. Depending on the circumstances, we may allow imports only through a preclearance program staffed by APHIS inspectors whose salaries are funded by the exporting country. 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. For these reasons, we have not amended the RMA that accompanies this final rule to discuss potential imports from other countries.

One commenter specifically noted that the requirements for Unshu oranges from Japan are not in harmony with the proposed rule.

The proposed rule and the risk management analysis are based on the most recent science and our determination of the appropriate level of protection for the citrus canker pathogen. We may reassess the risk associated with the importation of Unshu oranges from Japan in the future if Japan requests that we do so. If we reassess the risk associated with Unshu oranges from Japan, as discussed earlier,

the assessment will take into account all relevant local conditions and all pests that are present in Japanese citrus production areas.

It is important to note that Unshu oranges from Japan, if they are fumigated for arthropod pests, are allowed to be imported into commercial citrus-producing States, because they are produced under a systems approach. Fruit moved interstate from citrus canker quarantined areas is not allowed to be moved into those States under this final rule.

One commenter noted that the term "commercially packed" can be interpreted in different ways. In South Korea, the commenter stated, one group of growers used a "commercial" packing shed that was no more than 75 meters by 50 meters and in which the post-harvest treatment with sodium hypochlorite was performed in a small bath. The commenter stated that it is important to recognize that different circumstances prevail in different countries when harmonizing domestic regulations with import regulations.

We fully agree with the commenter that the circumstances in a country would need to be assessed before we could allow the importation of citrus from a citrus canker-affected area under conditions similar to those under which we are allowing the movement of citrus from a citrus canker quarantined area.

With regard to the specific circumstance cited by the commenter, we have determined that it is necessary to define the term "commercial packinghouse" in this final rule, given that the PRA and RMA analyzed the risk associated with the interstate movement of commercially packed fruit. In this final rule, we are adding a definition of *commercial packinghouse* to the regulations. This definition reads: "An establishment in which space and equipment are maintained for the primary purpose of packing citrus fruit for commercial sale. 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." This definition will help to ensure that the packinghouses that pack fruit for interstate movement under this final rule have equipment and operating procedures that are consistent with those described in the PRA and RMA.

Because the PRA and RMA referred specifically to the risks associated with commercially packed fruit, we are amending the proposed regulations in § 301.75–7 to refer specifically to commercial packinghouses.

One commenter stated that implementation of the proposed rule

may also result in foreign countries requesting APHIS to consider a similar approach for fresh commodities other than citrus. The commenter stated that the approach described in the proposed rule could be applied in any number of other situations in which a systems approach is not operationally or financially feasible.

It is important to note in response to this comment that we determine what phytosanitary mitigations are appropriate for the importation or interstate movement of commodities based on our assessment of the risk their importation or interstate movement poses and the appropriate level of phytosanitary protection against that risk. If we determined that a set of mitigations was necessary to provide the appropriate level of protection for a commodity proposed for importation, but that set of mitigations was determined not to be operationally or financially feasible by the national plant protection organization of the exporting country, we would not allow the importation of that commodity.

We would only allow the importation of a commodity under an approach similar to the approach used in this final rule if we determined that this approach could provide the appropriate level of phytosanitary protection. In past cases where we have determined that inspection, treatment, and limited distribution mitigations similar to those implemented in this final rule can provide an appropriate level of protection against the introduction of plant pests by imported commodities, we have employed such mitigations. For example, litchi imported from Thailand are inspected for a fungal pathogen, irradiated for arthropod pests, and prohibited from being imported or moved into Florida due to the litchi rust mite.

In order for us to determine that a packinghouse-centered approach provided an appropriate level of phytosanitary protection, we would have to determine that the biology of the pest supported such an approach and that the pest in question could be effectively detected by inspection of the commodity. In addition, other considerations may apply based on the level of risk we determine importation of the commodity to pose.

Miscellaneous Comments on the RMA

One commenter noted that, since viable *Xac* have been found in fruits with canker lesions that are imported into Europe, it is clear that the importation of symptomless fruits from canker-infected areas has a risk of introducing the disease if all the control

steps, carried out by many people at different times, are not always perfectly implemented.

The RMA concluded that the introduction and spread of *Xac* into other commercial citrus-producing States through the movement of commercially packed fresh citrus fruit from quarantined areas is unlikely. While fruit with visible canker lesions has likely been imported into the EU, the importation of citrus fruit from areas where citrus canker is present has not resulted in the introduction of the disease in the EU, despite the fact that all fruit imported into the EU is allowed to move to citrus-producing areas within the EU. (This is discussed in more detail in the RMA in Section 5.6.2, "International and Interstate Movement of Citrus Fruit.") In addition, treatment and inspection will both serve as effective mitigations against the potential of fruit moved interstate to introduce citrus canker to other States. Nevertheless, the RMA concluded that the evidence is not currently sufficient to support a determination that fresh citrus fruit produced in a *Xac*-infested grove cannot serve as a pathway for the introduction of *Xac* into new areas. That is why this final rule prohibits the distribution of fruit moved interstate from quarantined areas to commercial citrus-producing States.

In the RMA, we stated that there is no authenticated record of the movement of fresh fruit infected with *Xac* being related to the epidemiology of citrus canker disease. One commenter stated that pest-free areas are now established on the basis of a pest being "known (as demonstrated by scientific evidence) not to occur" rather than "not known to occur," and the same standard of evidence should apply to this statement; research should be conducted to establish this statement as fact.

We agree with the commenter's characterization of the process by which pest-free areas are established. Our statement was not meant to imply that we had positively established that fresh fruit infected with *Xac* has never served as a pathway for the transmission of citrus canker. Rather, it reflects the fact that no outbreaks of citrus canker have ever been attributed to the movement of infected fruit, despite the brisk global trade in such fruit. (The majority of outbreaks of citrus canker whose cause is known were caused by the movement of infected citrus nursery stock, rather than fruit.)

The RMA noted the Asian leafminer interacts with *Xac* by providing wounds that serve as infection courts in leaves and, to a lesser extent, fruit. Leafminer wounds create suitable microclimates

for *Xac* development, and leafminer-damaged leaves have more and larger lesions. One commenter asked whether injuries from the peel miner, an insect present in California, could result in higher infection of fruits.

Injuries from the peel miner would be likely to increase the susceptibility of fruit to infection, and increase the severity of the infection if they became infected. In terms of overall spread of citrus canker, the peel miner would not likely be as epidemiologically significant as the Asian leafminer, since leaves of citrus trees and plants are more susceptible to citrus canker infection than the peels of citrus fruit.

One section of the RMA discussed the effect of shipping and storage temperatures on *Xac* populations, concluding that typical shipping and storage temperatures reduce such populations. One commenter noted that pathologists are able to keep *Xac*-infected samples in refrigerators at 2 °C to 4 °C and still isolate the bacterium. The commenter stated that the emphasis of this section should be on the survival of the bacterium.

We agree with the commenter that cool temperatures do not necessarily cause mortality for *Xac*, and the RMA noted accordingly that such temperatures influence survival rather than stating that they inactivate the bacteria. However, in the context of an analysis of the likelihood of citrus fruit serving as a pathway for the introduction or spread of citrus canker, it is important to note that shipping and storage temperatures reduce *Xac* populations. In addition, commercial refrigeration is also quite dry, and *Xac* is highly influenced by humidity, so the dryness of refrigeration is more likely to have mortality effects than the cold.

The RMA stated that fruit are susceptible to citrus canker infection from petal fall until they are around 6 cm in diameter, and are most susceptible at a fruit diameter of about 2–4 cm. One commenter stated that fruit size cannot be related to susceptibility unless the variety is indicated, as some varieties (such as grapefruit) are bigger than others (such as mandarins).

We agree with the commenter, and we have amended the discussion in the RMA to state that fruit are susceptible to natural (stomatal) infection from petal fall until they are fully expanded (around 6 cm in diameter for some varieties), and are most susceptible after stomata form and fruit is in a stage of rapid expansion, a period of about 90 to 120 days (at a fruit diameter of about 2–6 cm for some varieties).

In discussing the international and interstate movement of citrus fruit, the

RMA noted that in 2004, India (where *Xac* is reported) shipped 8 metric tons of citrus to Ghana and 2 metric tons to South Africa, and that no outbreaks of *Xac* have been reported in any of the recipient countries. One commenter stated that the shipment of citrus from India to South Africa seems a dubious record.

These data were drawn from the Food and Agriculture Organization's "World trade and crop production statistics" database at <http://faostat.fao.org>. The commenter provided no further information establishing these records as dubious.

We also discussed the movement of fresh citrus from Florida during *Xac* outbreaks. One commenter asked whether the earlier shipments of Florida fruit were from canker-free areas, or at least canker-free areas of production under official control.

We noted in the RMA that these shipments of Florida citrus may have originated in areas of low prevalence or free of *Xac*. These shipments were required to originate in groves that had been certified to be free of *Xac* based on an inspection.

Comments on the Model in Appendix 1 to the RMA

As mentioned earlier, to assist in evaluating the options we identified for packinghouse-centered risk management, we prepared a quantitative model (Appendix 1 to the RMA) based on Florida production and shipping data to evaluate the efficacy of three levels of phytosanitary inspection in ensuring that fruit with visible canker lesions does not enter commercial citrus-producing States. The three inspection levels were determined by preliminary estimates of the Plant Protection and Quarantine program's Citrus Health Response Program staff of inspection levels that might be operationally feasible. The three inspection levels evaluated were 500 fruit per lot, 1,000 fruit per lot, and 2,000 fruit per lot. Statistically, randomized inspection of 500, 1,000 fruit, or 2,000 fruit per lot will ensure, with 95 percent confidence, that the proportion of undetected fruit with visible canker lesions in a cleared lot is no more than 0.75, 0.38, and 0.19 percent, respectively.

The outputs of the quantitative model were probability distributions. The model determined, with 95 percent confidence, that the total number of citrus fruit shipped from Florida to 5 citrus-producing States (Arizona, California, Hawaii, Louisiana and Texas) over a single shipping season would be 181,283,744 or less if

unlimited distribution is permitted. The model determined, with 95 percent confidence, that the number of *Xac*-symptomatic fruit reaching those 5 States in a single shipping season would be 633,152 or less at the 1,000 randomly sampled fruit inspection level. We anticipate that about double that number (approximately 1,266,304 or less) of *Xac*-symptomatic fruit would reach those States at the 500 fruit inspection level. About half that number (approximately 316,576 or less) would reach those States at the 2,000 fruit inspection level. The model further determined with 95 percent confidence that the number of symptomatic fruit reaching citrus-producing areas within those States in a single shipping season would be 2,135 or less at the 1,000 fruit inspection level, about double that number (approximately 4,270 or less) at the 500 fruit inspection level, and about half that number (approximately 1,067 or less) at the 2,000 fruit inspection level. (As discussed in Section 9.3.3.4 of Appendix 1 to the RMA, the actual acreage on which citrus is produced within a citrus-producing State is a small fraction of the total acreage of that State.) The base level inspection of 1,000 randomly sampled fruit per lot was adopted because it is operationally feasible with small adjustments to the current phytosanitary inspection process in Florida.

The potential for fruit with visible canker lesions to reach commercial citrus-producing States, coupled with the aforementioned uncertainty regarding fruit as a pathway, led to the determination that additional mitigations were required.

We received several comments from one commenter addressing the model in Appendix 1 to the RMA.

The commenter stated that the model failed to take into account the increased numbers of fruit that would be moved interstate from Florida and imported from citrus canker-affected areas in other countries, and thus underestimated the number of potentially infected fruit that could reach commercial citrus-producing States. The commenter cited another comment that estimated that the spread of canker has resulted in an additional 20 percent of Florida's total fresh citrus groves becoming ineligible for interstate movement under the regulations that were in place before the publication of this final rule. That 20 percent, that commenter stated, represents approximately 8 million 4/5-bushel cartons or an approximately \$80 million potential business opportunity under the proposal.

The comment estimating the potential increase in fruit moved interstate under this final rule is dealt with in more detail under the heading "Comments on the Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis" later in this document. We have concluded that the increase in the number of fruit that will be moved interstate under this final rule is likely much less than the commenter estimates, although we have been unable to quantify the probable increase.

This final rule does not change our requirements for the importation of citrus fruit from areas in other countries where citrus canker is present. Therefore, this final rule will not increase the amount of fruit imported from such areas. As stated earlier in this document under the heading "Potential Application of the Packinghouse-Based APHIS Inspection System to Imported Citrus," our analysis of the risk associated with the importation of citrus fruit from other countries where citrus canker exists under conditions similar to those in this final rule would be conducted separately from the analysis we conducted for the proposal and this final rule.

In Section 9.3.3.1 of Appendix 1, we determined probability distributions for the number of 4/5-bushel cartons shipped per growing season for each commercial citrus-producing State destination and variety of fruit. To determine the probability distributions, we used the minimum, average, and maximum values of the last 4 years (2003 through 2006) of historical data on citrus fruit shipping from Florida to other commercial citrus-producing States.

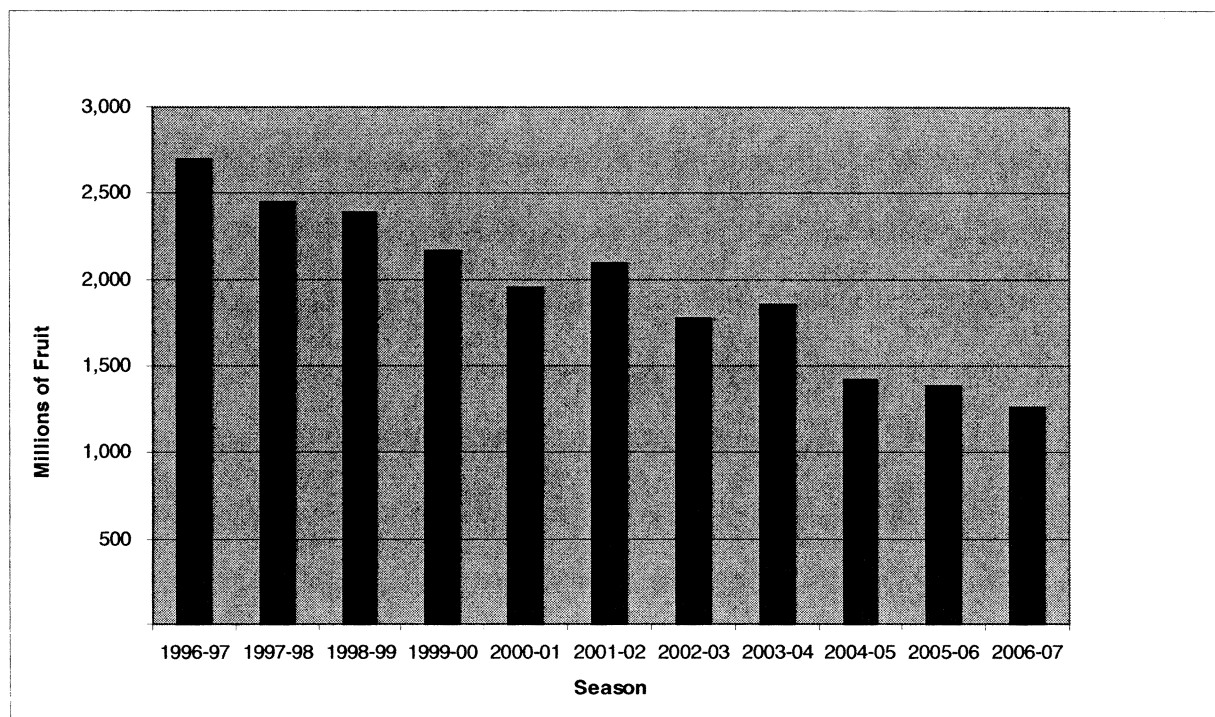
One commenter stated that the last 4 seasons of data have been strongly affected by both natural events (damage caused by hurricanes, tree destruction in an attempt to eradicate the canker outbreak) and imposed movement restrictions (due to the canker outbreak). The commenter noted that over the 10 years preceding the 2003 through 2006 data, the average domestic shipping quantity was 1.6 times higher than it was during those years. The commenter stated that the uncertainty in the expected average number of fruit that will be shipped from Florida is therefore considerably higher than would be expected from examination of just the last four seasons, unless APHIS considers that the decline in numbers is a permanent feature of the Florida industry and the last four seasons are typical.

The amount of citrus moved interstate has declined steadily since the 1996–97

season, with a larger decline in 2004–

05, when fruit production was affected by hurricanes. (See figure 1.)

Figure 1.—Amount of fruit moved interstate from Florida by year, 1996-97 through 2006-07 seasons



The trends and changes occurring in the Florida citrus industry suggest that the last four seasons are typical. The 2006 Commercial Citrus Inventory for Florida (USDA–NASS 2007) states the following about the 2-year trend for Florida citrus fruit production: “Florida’s citrus acreage peaked again at 857,687 in 1996 but has been declining ever since. The 2006 total is 621,373, down 17.0 percent in a 2-year period noted for hurricanes, diseases, and urban development. The net change, a loss of 127,182 acres, is the greatest in any non-freeze period and 2nd overall. The Indian River District bore one-third of this loss. Removals out-numbered new plantings by a ratio of more than 5:1. The 23,623 acres of new plantings are the least recorded in any two-year period since 1970–71.” The last two sentences are especially germane to this discussion, as any rebound in Florida fresh citrus production would depend on new plantings. The Commercial Citrus Inventory also states that acreage decreases were reported for all 30 counties included in the survey, and that “only 197,027 acres (28.2 percent) remain from the 697,929 reported in the 1988 census.” This evidence indicates a continued trend toward a decline in

Florida citrus production. Therefore, we are making no changes in response to this comment. However, as shipping data for the 2006–07 season are now available, we use those data in Appendix 1 of the RMA that accompanies this final rule.

In Section 9.3.3.2 of Appendix 1 of the RMA, we presented a determination of the number of fruit shipped per $\frac{1}{5}$ -bushel carton. We used USDA–National Agricultural Statistics Service (NASS) forecasts of fruit sizes to determine percentage distributions for the number of fruit that would be contained in each $\frac{1}{5}$ -bushel carton, and then used the minimum, mean, and maximum from each of these distributions as parameters in a Pert distribution to define the number of fruit of each variety per $\frac{1}{5}$ -bushel carton.

The commenter made several comments about this technique, stating that:

- The USDA–NASS forecasts of fruit sizes are properly represented by a discrete, rather than a continuous, distribution;
- No basis was given for the use of Pert distributions to account for the uncertainties in annual shipments;

- The Pert distributions generated have mean values that differ from the mean values of the data, because the mean values of the data were improperly used as the modes for the Pert distributions;

- The actual use of Pert distributions, which is accomplished by fitting the discrete data to a Pert distribution and then finding the mean and standard deviation of the Pert distribution, is inefficient, not well defined, and has an unknown error rate; and

- The Florida Department of Citrus has data on the actual average numbers of fruit per $\frac{1}{5}$ -bushel carton, which we should have used.

The commenter stated that these flaws had an impact on a later section of the analysis as well, Section 9.3.4, in which our evaluation of the uncertainty associated with the number of fruit that will move interstate from Florida relies on the uncertainty in the Pert distributions that the commenter stated were incorrectly employed.

We agree that the analysis would have been improved by the use of the actual average numbers of fruit per $\frac{1}{5}$ -bushel carton. To improve the model in Appendix 1 for this final rule, we have obtained from the Florida Department of

Citrus the total number of 4/5-bushel cartons of fruit for each type and size of fruit that was shipped to commercial citrus-producing States and the average number of fruit per bushel for each fruit

size. Our use of these data makes using the USDA–NASS fruit size forecasts and the resulting Pert distributions unnecessary, thus addressing the commenter's concerns.

For some varieties, using real data increases the number of fruit moved interstate; for other varieties, using real data decreases that number. A summary is provided in Table 1.

TABLE 1.—Q1: ANNUAL AMOUNT OF FLORIDA CITRUS BY VARIETY SHIPPED TO COMMERCIAL CITRUS-PRODUCING STATES

Variety	June 2007 approach	Current approach	Percentage change
Grapefruit:			
5th percentile	4,523,165	3,137,949	– 31
Mean	6,169,582	5,386,794	– 13
95th percentile	7,893,953	7,637,299	– 3
Oranges:			
5th percentile	20,948,908	13,525,400	– 35
Mean	25,081,498	19,351,870	– 23
95th percentile	29,425,176	25,158,470	– 15
Templets:			
5th percentile	91,786	103,295	13
Mean	242,332	438,078	81
95th percentile	392,884	773,018	97
Tangelos:			
5th percentile	241,718	395,323	64
Mean	406,334	804,408	98
95th percentile	575,434	1,210,151	110
Honey tangerines:			
5th percentile	78,052,912	58,535,060	– 25
Mean	88,549,976	68,711,030	– 22
95th percentile	99,601,208	78,917,320	– 21
Other tangerines:			
5th percentile	43,050,856	34,651,600	– 20
Mean	47,975,284	42,753,630	– 11
95th percentile	52,948,348	50,701,440	– 4

Taken together, these changes do not result in significant changes in the outputs of the model.

In Section 9.3.3.3 of Appendix 1 to the RMA, we estimated the true prevalence of symptomatic fruit in lots that are inspected, found to be free of visible canker lesions, and approved to enter interstate commerce. The true prevalence was based on the apparent prevalence (p_{apparent}), which was adjusted to account for inspection sensitivity. We used the beta distribution to estimate the apparent prevalence assuming a sample size of n fruit that are examined by inspectors. Since we are estimating the true prevalence in the lots of fruit that have been inspected and found to be free of visible canker lesions, $x = 0$, which means that the equation for the beta distribution we used was:

$$p_{\text{apparent}} = \text{Beta}(x+1, n-x+1) = \text{Beta}(1, n+1)$$

One commenter stated that such an estimate applies only to an isolated single lot, with no further information available, and does not apply to the system we proposed, in which many lots would be evaluated. The commenter stated that what is required is the average over many lots, where lots are either accepted or rejected, and takes

no account of the known fact of infected fruit being present.

The commenter suggested considering the issue in the following way: Suppose that the fruit entering the inspection process is infected at an incidence rate r , and this rate is the same for all fruit lots inspected. The inspection of n fruit will then fail to detect any infected fruit with probability $(1-r)^n$, and detect at least one infected fruit with probability $1-(1-r)^n$. The lot rejection rate for such fruit will thus be $1-(1-r)^n$, independent of the size of the lot. Accepted lots will be passed to market (still with infection rate r), and rejected lots will be dealt with in some other way. The commenter stated that this meant that any infection rate whatever can occur in the accepted lots; the controlling factor is likely to be the economically acceptable rejection rate. The commenter also raised issues related to the disposition of lots that are not approved to enter interstate commerce.

The approach suggested by the commenter provides results that are equivalent to the procedure that we used. Under the assumption used by the commenter, the Beta distribution method we used indicates that while any prevalence can theoretically occur in accepted lots, 97 percent of lots approved for shipment would have a

true prevalence of fruit with visible canker lesions of less than 0.004 (0.4 percent). The method presented by the commenter indicates that a lot with a true prevalence of fruit with visible canker lesions of 0.004 has a 97 percent probability of being rejected.

We do not consider the prevalence of fruit with visible canker lesions in rejected lots because those fruit are not approved for shipment outside the quarantined area; this final rule explicitly prohibits reconditioning and resubmitting fruit for inspection (see the discussion under the heading “Reconditioning” later in this document). Furthermore, it is not necessary to know the prevalence of symptomatic fruit produced in the quarantined area in order for APHIS inspection to ensure that fruit shipped outside the quarantined area has a high probability of containing a low prevalence of symptomatic fruit. If the prevalence were to increase (or decrease), APHIS inspection would result in a higher (or lower) rate of lot rejection.

The commenter stated that the analysis was flawed because it did not address fruit contaminated with surface bacteria, fruit with wounds that could be infected with citrus canker, and fruit with lesions smaller than 1 mm.

For the reasons we discussed earlier in this document under the headings “Treatments and Surface Contamination With *Xac*” and “Inspection and Potential for Mature Fruit Without Visible Lesions to Serve as Pathway for Infection,” we have determined that these fruit are not likely to be an epidemiologically significant pathway for the introduction or spread of citrus canker; in the case of wounded fruit or fruit with lesions smaller than 1 mm, we have also determined that such fruit are unlikely to occur in real-world conditions. Therefore, we do not consider them in the model in Appendix 1 to the RMA that accompanies this final rule.

In Section 9.3.3.4 of Appendix 1 to the RMA, we used a model to determine the proportion of fruit with visible canker lesions shipped to citrus-growing areas within commercial citrus-growing States, based on the amount of citrus-bearing acreage (including acreage for backyard trees) in each citrus-producing county, the human population in each citrus-producing county and commercial citrus-producing State, and the area of each citrus-producing county.

The commenter stated that we had only considered in our analysis those counties for which the production acreage is reported in the NASS statistics, and that those counties or parishes with commercial production that are listed in the NASS statistics, but for which production acreage is not reported to prevent inferences about individual farms, should have been included in the model.

We agree with the commenter. While acreage is not available for these counties, NASS does report the number of farms in the counties. We have multiplied the number of farms by the mean farm size in the State in each of the counties in which farms were reported to estimate the citrus-producing acreage within each of those counties. We then added that acreage to the model. This results in an approximately 10 percent increase in the total citrus-producing acreage included in the model.

We attempted to model backyard citrus acreage in order to determine what proportion of fruit is consumed in reasonably close proximity to *Xac* host trees outside of commercial citrus production areas. Having estimated the backyard citrus acreage, we added it to commercial citrus production acreage data in order to determine the total citrus-bearing acreage in the county. We then used the proportion of citrus-bearing acreage in a county to the total acreage in a county to estimate how

much of the citrus that is moved to a county is consumed in the citrus-bearing acreage.

The commenter stated that, rather than using acreage to determine how much citrus is consumed in reasonably close proximity to *Xac* host trees, we should use population. The commenter stated that consumption of citrus is definitely not uniform over the area of the county, but rather is concentrated where the population is. The commenter stated that the approach of prorating consumption by area fails entirely to account for the proximity of a large fraction of the population to citrus plant material (including backyard trees). The commenter suggested using data from the RMA and data on average household size for owner-occupied houses to estimate the fraction of the population living in owner-occupied houses with backyard citrus trees within counties containing commercial citrus groves.

The model used in the RMA makes a simplifying assumption that fruit consumption occurs randomly throughout the area of each county in which citrus is produced. Admittedly, this is an imperfect estimate. However, the alternate simplifying assumptions presented by the commenter—that all fruit consumed by residents of households where citrus trees are present is consumed in residential dooryards—would result in a great overestimate of the proportion of citrus consumed in reasonably close proximity to *Xac* host trees. Such an assumption would imply that residents of households in citrus-producing counties do not consume fruit indoors (at work, at school, in restaurants, or inside their homes), and that they do not discard the peel of the consumed fruit in a trash can. For example, the commenter’s assumption results in an estimate that 13.6 percent of fruit consumed in Arizona would be consumed and disposed in reasonably close proximity to *Xac* host trees.

The commenter’s suggested methodology thus assumes the maximum possible exposure. The Presidential/Congressional Commission on Risk Assessment and Risk Management observed that the use of unrealistic maximum exposure scenarios impairs the scientific credibility of risk assessment (CRARM 1997b).

We are making no changes to the model in Appendix 1 of the RMA in response to this comment. We believe the assumptions we used are reasonable, if imperfect. However, it is important to note that the model was used to evaluate Option 2, which would have

provided for unlimited distribution of fruit from the quarantined area, subject to treatment and APHIS inspection. If we were able to determine that the assumption we used to determine how much fruit is consumed in reasonably close proximity to *Xac* host trees resulted in an underestimate, the conclusions drawn from the model would not change: Some fruit with visible canker lesions would be consumed in reasonably close proximity to *Xac* host trees.

With the modifications described here, the model in Appendix 1 of the RMA that accompanies this final rule has determined, with 95 percent confidence, that the total number of citrus fruit shipped from Florida to 5 citrus-producing States (Arizona, California, Hawaii, Louisiana and Texas) over a single shipping season would be 152,358,900 or less if unlimited distribution is permitted. The model determined, with 95 percent confidence, that the number of fruit with visible *Xac* lesions reaching those 5 States in a single shipping season would be 514,229 or less at the 1,000 fruit inspectional level. The model further determined with 95 percent confidence that the number of fruit with visible *Xac* lesions reaching citrus-producing areas within those States in a single shipping season would be 1,747 or less at the 1,000 fruit inspectional level.

As the original model did, the revised model indicates that, under unlimited distribution, fruit with visible canker lesions would be moved interstate from Florida into citrus-producing areas within commercial citrus-producing States. Given that the evidence is not currently sufficient to support a determination that fresh citrus fruit produced in a *Xac*-infested grove cannot serve as a pathway for the introduction of *Xac* into new areas, the model in Appendix 1 to the RMA continues to support our selection of Option 4.

Comments on the Proposed Regulatory Provisions and Other Comments

Program Monitoring and Review

Four commenters requested that APHIS put in place some type of program review if the provisions of the proposed rule were implemented. Three requested that the program allowing the interstate movement of fruit from a quarantined area under the conditions described in the proposal be a pilot program that would last for 2 years, after which a comprehensive performance review could be conducted to determine whether to extend the program. One commenter requested that a program

review be conducted after each of the first two shipping seasons under the program.

APHIS recognizes the value of periodic program reviews to assess performance and effectiveness. As discussed earlier, although the safeguards we proposed will be highly effective at preventing the interstate spread of citrus canker, we are planning monitoring and disease surveillance activities to ensure that the program is indeed effective. If we determine that part or all of the program is not meeting our expectations, we have the option to amend the regulations accordingly. Given this, we do not agree that it is necessary to limit the amount of time the program will be in place through the regulations.

One commenter recommended that APHIS provide funding for additional surveys for citrus canker in commercial citrus-producing States to provide those States with evidence allowing them to declare freedom from citrus canker and to quickly detect the disease if it spreads. The commenter stated that, in the event that citrus canker spreads to other States, there will be a need for similar regulations to protect those States where the disease is not present.

We are providing funding for citrus canker surveys in susceptible States. We have also worked with commercial citrus-producing States to develop emergency response guidelines should citrus canker be found in those States, and we will continue to review and refine those guidelines to ensure that they will be effective in the event of a detection.

The regulations presently in place provide standards and requirements sufficient to prevent the spread of citrus canker from any area in the United States that might be quarantined for citrus canker, not just for the State of Florida.

One commenter stated that, before implementing the packinghouse-centered approach for regulating fruit described in the proposed rule, APHIS should propose and seek review for the approach through the North American Plant Protection Organization (NAPPO) and the International Plant Protection Convention (IPPC).

NAPPO facilitates cooperation and the development of standards among the national plant protection organizations of Canada, the United States, and Mexico, and the IPPC performs a similar function for the wider international community. Neither body has the authority to set regulatory policy for the United States. We conducted our risk analyses and developed the proposed rule on the basis of the available science

and the conditions prevailing in areas quarantined for citrus canker within the United States.

Reconditioning

In the proposed rule, we asked for comments on reconditioning (i.e., treating and culling fruit again after its initial treatment and culling). The proposed regulations left open the issue of allowing a lot of fruit that was initially found to be ineligible for interstate movement to be reconditioned and resubmitted for inspection. Because we had not thoroughly examined all operational aspects of the reconditioning of fruit, we invited comments on this topic.

We received five comments on the issue, all of which supported allowing the reconditioning of fruit. None of the commenters provided guidance on any specific circumstances in which reconditioning should be allowed.

After careful consideration of the issues involved in reconditioning, we have decided not to provide for reconditioning of rejected fruit in this final rule. One of the purposes of the APHIS inspection requirement is to give growers and commercial packinghouses an incentive to supply fruit free of visible canker lesions for interstate movement. If we allow a lot of fruit that has been rejected to be reconditioned and resubmitted for inspection, the incentive to provide fruit free of visible canker lesions substantially diminishes. Reconditioning could also provide the packinghouse with a greater incentive to "take its chances" in submitting a lot of fruit that may contain visible canker lesions for inspection. Therefore, allowing reconditioning could weaken the protection provided by the APHIS inspection. Additionally, if fruit undergo surface disinfectant treatment multiple times, residues of the disinfectant may exceed EPA tolerances; it would be difficult to control how many times fruit came into contact with surface disinfectants if we allowed reconditioning. For these reasons, we are not allowing reconditioning in this final rule.

Definition of Lot

We proposed to define the term *lot* as "The inspectional unit for fruit composed of a single variety of fruit that has passed through the entire packing process in a single continuous run not to exceed a single workday (i.e., a run started one day and completed the next is considered two lots)."

One commenter asked that the rule allow commercial packinghouses flexibility and discretion in working with APHIS to define specific lot and

sample sizes and define the inspection process, as different operational issues exist in each packinghouse.

We appreciate this commenter's concern. The compliance agreement under which a commercial packinghouse must operate in order to be eligible to pack fruit for interstate movement under this final rule will provide a great deal of flexibility in defining lot size and meeting the inspection requirements.

One commenter asked whether the definition would mean that fruit from several growers will be considered one lot by APHIS if the fruit is of the same variety and packed on the same day. The commenter also asked whether the definition would mean that, if symptomatic fruit is found packed in a lot, then fruit from all the growers for that variety packed on that day will be ineligible for interstate commerce, even if the fruit from the groves of some growers did not have detectable lesions.

Packinghouses are free to define their lots as less than the amount of each variety of fruit that is packed in 1 day if they wish. Under the compliance agreement that packinghouses will be required to have in place, packinghouses must provide notice to APHIS about the estimated sizes of the lots they are running; APHIS will not set lot sizes itself. Regardless of the size of a lot, APHIS will inspect the lot at a rate 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.

If any symptomatic fruit are found in a lot, as the lot has been defined by the packinghouse in accordance with the definition of *lot* in § 301.75-1 and the provisions of the compliance agreement, then all fruit in that lot will be ineligible for interstate commerce, regardless of whether the lot is composed of fruit from one or from several sources. This provides an incentive for growers and packinghouses to ensure that each lot contains no fruit with detectable lesions.

One commenter stated that the proposed definition of *lot* is vague and not consistent with the definition of *lot* in the IPPC's Glossary of Phytosanitary Terms.⁷ The commenter recommended that the definition be clarified, by variety, in the final rule.

While APHIS always considers the IPPC Glossary when determining how to

⁷ See the International Glossary of Phytosanitary Terms (2007), which is International Standard for Phytosanitary Measures (ISPM) Number 5. To view this ISPM on the Internet, go to <http://www.ippc.int/IPP/En/default.jsp> and click on the "Approved standards" link under the "Standards (ISPMs)" heading.

define a term, our use of the term "lot" in the proposal is consistent with U.S. citrus industry practices; using another term would likely provoke unnecessary confusion. There is no phytosanitary or statistical reason to set lot sizes by variety.

We stated in the proposal that we intend to inspect fruit at a rate of inspection 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. This is equivalent to randomly sampling 1,000 fruit per lot.

One commenter stated that it is essential that APHIS establish the maximum lot size that could be run with only 1,000 fruit inspected. The commenter stated that leaving the establishment of a lot size to packinghouse discretion creates the potential for a wide variation in the number of fruit actually cleared by APHIS inspectors. The commenters stated that it is obvious that a lot size of 200,000 pieces of fruit is considerably different than one of 50,000, because the potential for infected pieces of fruit to slip through the treatment and inspection steps is four times as great in the latter case.

It may seem counterintuitive that randomly sampling the same number of fruit for a lot composed of 50,000 fruit and a lot composed of 200,000 pieces of fruit provides the same confidence of detecting fruit with visible canker lesions at the 0.38 percent prevalence level. However, as discussed in Section 9.3.3.3 of Appendix 1 to the RMA, the hypergeometric sampling algorithm (which assumes that the fruit is sampled without being returned to the lot, thus ensuring that the same piece of fruit is not inspected twice) indicates that randomly sampling 1,000 fruit is adequate to detect, with a 95 percent level of confidence, any lot of fruit containing 0.38 percent or more fruit with visible canker lesions for any lot of 100,000 fruit or more. For lot sizes less than 100,000 fruit, randomly sampling 1,000 fruit actually gives better than 95 percent confidence of detecting the prevalence of 0.38 percent.

The reason this is true can be seen by imagining a large barrel and a small keg, both of which are filled with marbles. The barrel holds a million marbles, while the keg only holds 10,000 marbles. In both the barrel and the keg, though, 99.9 percent of the marbles are white and 0.1 percent are black. If one randomly samples the same number of marbles from both the barrel and the keg, one has the same chance of drawing a black marble from either the barrel or the keg. Even though there are 100 times

more total marbles in the barrel, the proportion of white marbles to black marbles is the same in both the barrel and the keg. Similarly, we have designed the sampling procedure to detect fruit with visible canker lesions at a targeted prevalence of 0.38 percent; while we do not know the prevalence of fruit with visible canker lesions in any lot, the prevalence at which our sampling protocol will detect fruit with visible canker lesions is fixed. Thus, randomly sampling 1,000 fruit from a lot is appropriate for both lots composed of 50,000 fruit and lots composed of 200,000 fruit, because the targeted prevalence of 0.38 percent or more fruit with visible canker lesions is the same for each lot.

It should be noted that, in cases where fruit cannot be randomly sampled (for example, when fruit has already been packed in boxes for shipping), inspection of more than 1,000 pieces of fruit may be necessary in order to inspect the lot at a rate 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. We will communicate inspection requirements to packinghouses as part of the implementation of the compliance agreements.

One commenter stated that the statistical sampling procedure described in the proposed rule was not appropriate for lots packed by gift fruit packers, as such lots are very different from large-scale commercial lots.

We intend to inspect fruit at a rate of inspection 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. This is equivalent to randomly sampling 1,000 fruit per lot for most lots. However, for smaller lots, the number of fruit that must be randomly sampled to detect, with a 95 percent level of confidence, a lot of fruit containing 0.38 percent or more fruit with visible canker lesions could be less than 1,000, as discussed in Section 9.3.3.3 of Appendix 1 to the RMA. This principle may be applicable to gift fruit lots, which are sometimes smaller than 1,000 fruit. For lots larger than 1,000 fruit, the statistical principles behind determination of how many fruit must be inspected to achieve this detection level apply regardless of whether the fruit is from a gift packer or a larger packinghouse.

We are making one change to clarify the requirement for the inspection level. The proposed rule stated that we would require the number of fruit to be inspected to 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. This is the level of inspection that we will be conducting as of the publication of this final rule. However, we also included provisions allowing the inspection of another quantity that gives a statistically significant confidence of detecting the disease at a level of infection to be determined by the Administrator. In the preamble to the proposed rule, we stated that "If at some time in the future conditions warrant changing this rate of inspection, APHIS would provide for public participation in that process through the publication of a notice in the **Federal Register**." To make our process for changing the inspection level clear in the regulations, this final rule adds a footnote to the regulations that includes the information regarding the other sampling level and the information that appeared in the preamble to the proposed rule.

Dooryard Fruit

We stated in the proposal that our proposed provisions would allow any Florida citrus growers, including commercial, gift fruit, and dooryard growers, to move their fruit interstate to States other than commercial citrus-producing States provided they comply with the conditions discussed in the proposed rule. Dooryard growers are typically homeowners who have citrus trees in their yards and wish to ship the fruit from those trees interstate to friends or family. The regulations in place before the publication of this final rule required fruit moved interstate to originate from a grove that had been inspected and found to be free of citrus canker and required vehicles, equipment, and other articles used in the grove to be treated upon leaving the grove. Since dooryard growers could not comply with these requirements, the interstate movement of dooryard fruit was effectively halted.

One commenter submitted comments on the regulations in place before the publication of this final rule, stating that dooryard growers should be allowed to ship fruit interstate under these conditions:

- Inspectors could certify dooryard trees as free of citrus canker upon request.
- Surface disinfectant treatment would not be required if the tree was certified as free of citrus canker.
- Dooryard fruit would be permitted to be moved only to States other than commercial citrus-producing States.
- The number of boxes a dooryard grower could ship in a season would be restricted to 20.

The regulations promulgated in this final rule do not distinguish between dooryard growers and commercial growers for the purposes of moving fruit interstate. Anyone can move fruit interstate if he or she has the fruit packed at a commercial packinghouse and treated and inspected as described in the amended regulations.

The approved disinfectants listed in the regulations in § 301.75–11(a) reduce numbers of *Xac* cells to low or undetectable levels on citrus fruit moving interstate from citrus canker quarantined areas. The APHIS inspection can detect, with a 95 percent level of confidence, any lot of fruit containing 0.38 percent or more fruit with visible canker lesions. These restrictions are necessary to address the risk associated with the interstate movement of fresh citrus fruit from a quarantined area. We expect that some commercial packinghouses will establish processes under which dooryard fruit can be treated and inspected to allow it to move interstate.

Two commenters objected to allowing dooryard fruit to be moved interstate from a quarantined area. One noted that the RMA considered the risk associated with commercially packed fruit, but we proposed to allow the movement of dooryard fruit under the same conditions. The other commenter stated that there is nothing in the proposed rule that provides any degree of confidence that dooryard fruit will not be shipped from Florida and that in all likelihood dooryard fruit will not be treated with an approved surface disinfectant in a packinghouse.

The RMA addressed the risks associated with commercially packed fruit; accordingly, we are only allowing the movement of dooryard fruit if it is commercially packed, treated, and inspected by APHIS. Like commercial fruit growers, dooryard fruit growers have an incentive to supply fruit that is free of visible canker lesions, as any lot of fruit that is found through inspection to contain fruit with visible canker lesions will be ineligible for interstate movement. We will conduct outreach efforts to ensure that dooryard growers are aware of the new requirements.

Gift Fruit Packers and Compliance Agreements

One commenter, a gift fruit packer, stated that the proposed regulations were written primarily for the 50 large citrus packing operations registered with the State of Florida rather than the 92 small citrus packinghouses that are also registered with the State. The commenter specifically stated that several of the provisions of the

compliance agreement described in the proposal would pose difficulties for smaller packinghouses, including the requirements for:

- Notice of estimated lot size and run times;
- Need for notice when APHIS inspectors are not present on a regular basis;
- Need for notice when there are significant changes in the amount of fruit being packed;
- Provisions for holding fruit when packing is done at a time when an APHIS inspector is not present; and
- Hours of coverage for APHIS packinghouse inspections.

The commenter noted that packages of gift fruit often incorporate citrus of multiple varieties, and that random sampling of packed boxes is not an option at gift fruit packinghouses, since once the fruit is boxed, the boxes are glued and labeled for shipping.

The commenter expressed specific concerns about the sporadic nature of operations for many smaller packinghouses, which run fruit when there are orders to be filled for most of the year and then run constantly during the busy season in December. Since we proposed to require that an APHIS inspector would have to be present whenever a packinghouse was operating, the commenter was concerned that the gift fruit packinghouses might not be able to provide notice of the need for an inspector during the slow times and then might be left without the services of an inspector during busy times. Another commenter also expressed general concerns about the availability of inspectors.

We appreciate the commenter bringing these issues to our attention. It has always been our intention to design a system suitable for both large and small commercial packinghouses. We are aware of the packing patterns of the smaller packinghouses and are planning our inspection staffing accordingly. We can address all the issues raised by the commenter in the context of the compliance agreement, which will provide a great deal of flexibility in how an individual operation can fulfill this final rule's treatment and inspection requirements.

As discussed in the proposed rule, in the compliance agreement, the owner or operator of the packinghouse will agree to treat fruit to be moved interstate with one of the approved treatments according to the procedures specified in § 301.75–11, and to see that this fruit is packed only in boxes marked in accordance with the requirements in § 301.75–7(a)(6). The compliance

agreement will also contain (but not to be limited to) specific provisions pertaining to:

- Access to the facility, and to necessary records and documents by APHIS inspectors;
- Means by which lots are designated and notice of estimated lot sizes and run times;
- Need for notice when APHIS inspectors are not present on a regular basis;
- Need for notice when there are significant changes in the amount of fruit being packed;
- Conditions (access to fruit, lighting, safety, etc.) that must be met in order for APHIS inspectors to carry out the required inspections;
- Provisions for handling and storage of fruit, including provisions not allowing the movement of any part of a lot from the packinghouse until APHIS inspection is complete;
- Hazard-free access to treatment areas so that APHIS inspectors can monitor the concentrations of chemicals used for fruit treatment;
- Provisions for holding fruit when packing is done at a time when an APHIS inspector is not present; and
- Hours of coverage for APHIS packinghouse inspections.

Using the compliance agreement to provide conditions for implementing the regulations will give APHIS some flexibility to accommodate packinghouse procedures. For example, in the compliance agreement, we will allow commercial packinghouses to work with APHIS to determine methods for sampling the fruit. For gift fruit packers, we would sample each lot of fruit before it is packed into boxes. Once a lot is inspected by APHIS and approved to enter interstate commerce, fruit from the lot can be combined with fruit from other lots that have been inspected and approved, in any way that is convenient for the packer; all that is required is that all the fruit so combined be from lots that have been inspected by APHIS and approved to enter interstate commerce.

Boxes or Other Containers

We proposed that, in order to be moved interstate, regulated fruit would have to be packaged in boxes or other containers that are approved by APHIS and that are used exclusively for regulated fruit to be moved interstate.

One commenter, a gift fruit packer, was concerned that the boxes used by such packers are not similar to the boxes used by large packinghouses. The commenter recommended that the issue be worked out somehow, perhaps by

exempting gift fruit from the requirement.

APHIS has the option to approve any boxes or containers. We are not aware of any boxes used by gift fruit packers that would not be approved. The use of the limited permit statement on boxes or other containers will indicate that the container has been approved by APHIS.

Limited Permits and Marking of Boxes or Other Containers

We proposed to require that the boxes or other containers in which regulated fruit is packaged for interstate movement would have to be clearly marked with the statement "Limited Permit: USDA-APHIS-PPQ. Not for distribution in AZ, CA, HI, LA, TX, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands of the United States." (The regulations in place before the publication of this final rule did not include the "Limited Permit: USDA-APHIS-PPQ" portion of that statement.) The proposed provisions also stated that only fruit that meets all of the requirements of the section may be packed in boxes or other containers that are marked with the above statement. We proposed these additional provisions in order to help ensure that only fruit that has been handled in accordance with all of the requirements described in § 301.75-7 would be packaged in boxes or other containers bearing the limited permit statement.

One commenter stated that the use of the term "Limited Permit" on shipments of gift fruit would be unnecessarily legalistic in the context of gift fruit shipments, which are addressed to specific people in States other than commercial citrus-producing States. The commenter suggested that we either retain the language that had been in place at the time the proposed rule was published or allow gift fruit shipments to use language like "Please don't take any of your fruit to citrus-producing areas in the United States, which are AZ, CA, HI, LA, TX, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands."

We appreciate the commenter's concerns and agree that the risk of gift fruit shipments being sent to a commercial citrus-producing State is likely to be extremely low. However, adding the "Limited Permit: USDA-APHIS-PPQ" statement to the boxes or other containers in which regulated fruit is moved interstate allows us to ensure that the statement appears only on boxes or other containers filled with fruit that is eligible for interstate movement. Therefore, we consider this statement to be an essential part of our

efforts to ensure that fruit that is moved interstate meets all the requirements in the regulations.

Nine commenters did not object to the labeling change, but stated that the fact that their current inventory of boxes and other containers does not include the "Limited Permit: USDA-APHIS-PPQ" statement would pose a problem for them in complying with the new regulations. One of the commenters, a representative of Florida commercial packinghouses, stated that the current inventory of boxes and other containers with the old markings is worth \$2 to \$2.5 million. These commenters requested that we allow them to use up their current inventory of containers while box and container manufacturers retool their equipment to produce containers with the new statement.

We appreciate the concerns of these commenters as well. We note that this final rule requires only that the boxes or other containers approved by APHIS be marked with the statement, not that the statement be printed directly on the boxes or other containers; if commercial packinghouses have inventories of boxes or other containers without the "Limited Permit: USDA-APHIS-PPQ" statement, they can add that statement through means such as a sticker or stamp, as long as the statement is clearly marked.

However, it is not practical to modify bags of fruit in this manner, as the distribution statement printed on bags is often small or attached to the bag, and the limited permit statement often cannot be added to it. For this reason, we are temporarily allowing fruit to be packed for interstate movement in bags if those bags are clearly marked with the distribution statement and if those bags are then packed in a box that is marked with both the limited permit statement and the distribution statement. Fruit will only be allowed to be packed in bags that are marked with the distribution statement if that fruit is eligible for interstate movement. Because the bags must be packed in boxes that are marked with both the limited permit and the distribution statements, and because bagged fruit is not unloaded from the boxes in which it is shipped until it reaches the point of sale, we believe that this requirement will provide the same level of protection against illegal movement of fruit from the quarantined area as the requirement in the proposed rule, while allowing some flexibility for regulated parties.

As the commenters requested, this exemption is temporary; it will expire on August 1, 2008. After that date, all fruit intended for interstate movement will be required to be packed in boxes

or other containers that are clearly marked with both the limited permit and distribution statements.

In this final rule, we are also providing that fruit that is not eligible for a limited permit may not be packed in boxes that are marked with only the distribution statement. This means that either fruit are eligible for a limited permit, in which case they must be packed in boxes that are marked with the limited permit and distribution statements, or ineligible, in which case neither of these statements may appear on the boxes. Fruit that is not eligible for a limited permit and is moved for intrastate sale or for export can be packed in the same boxes or other containers, including bags, as fruit that is eligible for interstate movement, as long as the limited permit and distribution statements are removed or obscured (through means such as opaque ink or a sticker) before the fruit is shipped.

As mentioned earlier in this document under the heading "Pest Risk Assessment and Risk Management Analysis," this final rule also requires the limited permit and distribution statements to be printed on any shipping documents accompanying the fruit.

Movement of Regulated Fruit Through Commercial Citrus-Producing States

The regulations do not currently provide for the movement of regulated fruit through commercial citrus-producing States for ultimate shipment to other States (i.e., transshipments). We did not propose to provide for such movement in the proposed rule.

One commenter requested that the final rule provide for such movement. The commenter stated that, while the concerns of commercial citrus-producing States should be addressed through safeguards, the commenter believed allowing transshipments with suitable safeguards is consistent with the National Plant Board's Principles of Plant Quarantine. Another commenter stated that the proposal and RMA did not address transshipments via consumer modes.

We did not consider the risk associated with transshipment in the proposed rule. We would need to determine the risk associated with transshipment and how it could be mitigated before adding provisions for transshipment to the regulations. Therefore, it is not appropriate to provide for transshipment in this final rule. We plan to examine the risks associated with transshipment and, if our examination indicates that transshipment can be accomplished

safely under certain conditions, propose to provide for it in a future rulemaking.

Kumquats With Foliage

The regulations require regulated fruit moved interstate from a quarantined area to be free of leaves, twigs, and other plant parts, except for stems that are less than one inch long and attached to the fruit. We did not propose to change this requirement.

One commenter requested that the final rule allow the interstate movement of kumquat fruit with decorative foliage to States other than commercial citrus-producing States under a limited permit and with product inspection. The commenter stated that such movement would pose no appreciable risk, as this foliage is resistant to citrus canker and not used for propagation.

Foliage is subject to infection by citrus canker, and thus the risk posed by foliage would need to be evaluated before we could determine whether to allow its movement from the quarantined area. We did not address the risk posed by citrus foliage in any of the documentation accompanying this proposed rule. Therefore, it would be inappropriate to provide for the movement of citrus foliage in this final rule.

In response to the comment, we plan to examine the risks associated with the interstate movement of citrus foliage from quarantined areas. If we decide that the movement of citrus foliage can be accomplished safely under certain conditions, we would propose to provide for it in a future rulemaking.

Citrus Greening

One commenter stated that we should not put in place any rule allowing the interstate movement of fruit from Florida until we have a program in place to address the risk posed by citrus greening.

Restrictions on the movement of certain articles due to the presence of citrus greening have been put in place under separate Federal orders; the initial order was issued on September 16, 2005, and was updated on May 3, 2006. We further updated our restrictions relating to citrus greening through a Federal order issued on November 2, 2007, to expand the areas under quarantine due to the presence of citrus greening and the areas under quarantine due to the presence of the Asian citrus psyllid, a vector for the spread of citrus greening.

We have received reports of preliminary scientific evidence indicating that, when seedlings are generated from seed that is taken from plants infected with citrus greening, a

small percentage of those seedlings are themselves infected with citrus greening. In response to this evidence, we have also amended the Federal order to prohibit the movement of seed for planting from areas quarantined for citrus greening.

We are currently evaluating the preliminary evidence to determine whether seed contained in fruit may serve as a pathway for the transmission of citrus greening disease, and, if so, what restrictions may be appropriate for the movement of fruit from areas quarantined for citrus greening. Any regulatory action we may take in response to this evidence would be taken separately from this rulemaking, which addresses the risk posed by the interstate movement of citrus fruit from areas quarantined for citrus canker.

Miscellaneous Change

The regulations in § 301.75–7(a)(5) have required that all vehicles, equipment, and other articles used in providing inspection, maintenance, harvesting, or related services in a grove in which regulated fruit are produced for interstate movement must be treated in accordance with § 301.75–11(d) upon leaving the grove. This paragraph has also provided that all personnel who enter the grove or premises to provide these services must be treated in accordance with § 301.75–11(c) upon leaving the grove. We did not propose to change these requirements in the proposal. However, these requirements are inappropriate for the packinghouse-centered approach that we are adopting in this final rule. Accordingly, this final rule removes paragraph (a)(5) from § 301.75–7. It should be noted that growers will still have an incentive to perform such treatments, as they would help ensure that fruit produced in the grove remains free of visible canker lesions and thus eligible for interstate movement.

Comments on the Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis

In accordance with the requirements of Executive Order 12866 and the Regulatory Flexibility Act, we prepared a preliminary regulatory impact analysis and initial regulatory flexibility act analysis for the proposed rule.

Two commenters stated that this analysis was incomplete as it did not analyze the potential effects of the introduction of citrus canker into commercial citrus-producing States other than Florida. One commenter stated that costs involved with copper sprays, isolation fencing, and spraying for disinfection could take away the

current narrow margins that citrus producers enjoy, and that monitoring and surveying utilizing very high-cost labor would be very expensive. One commenter stated that the current canker-free status of California gives that State an advantage in the fresh citrus marketplace for exports.

We do not expect that the conditions in this final rule will result in the introduction of citrus canker into other commercial citrus-producing States, as the final rule retains the prohibition of the shipment of regulated fruit from a quarantined area to other commercial citrus-producing States. For that reason, we have not analyzed the possible effects of a citrus canker introduction on California citrus, including on California citrus producers' ability to export their fruit.

The use of copper sprays is already an industry practice to control other pests of citrus fruit. Further, copper sprays, isolation fences, and spraying for disinfection, while not required by APHIS, are considered to be best industry practices that help to prevent infestation by other pests. Incorporating best management practices into production practices benefits both the individual producer and the industry as a whole.

Grove surveys should be conducted regardless of the citrus canker status of any grove because early detection of any disease (such as citrus canker, citrus greening, citrus variegated chlorosis, and other diseases) is key to successful eradication of the disease.

One commenter, from Florida, estimated that the spread of canker has resulted in an additional 20 percent of Florida's total fresh citrus groves being declared ineligible to ship fruit interstate under the regulations that were in place before the publication of this final rule. That 20 percent, the commenter stated, represents approximately 8 million 4/5-bushel cartons or an approximately \$80 million potential business opportunity under the proposal.

Another commenter cited this figure and compared it to what the commenter stated was the billion-dollar California fresh citrus industry, indicating that the latter should not be risked for the benefit of the former. This commenter also noted that we characterized as small the changes to the supply of Florida fresh citrus in States other than commercial citrus-producing States resulting from additional shipments that would be newly eligible to move interstate under the proposed rule. The commenter asked why the rule was being rushed into place given the precedent the rule sets and the fact that

stakeholders would not be able to review the peer review comments before the publication of the final rule.

While the change from grove inspections to APHIS packinghouse inspections of finished fruit will allow Florida growers to maintain the quantity of fresh citrus that is eligible for interstate movement, and may result in an increase in that quantity, we do not expect that interstate shipments of fresh citrus will increase by a proportion equivalent to the potential production for the fresh market from groves previously prohibited from shipping interstate due to citrus canker. Rather, APHIS expects the quantities of fresh citrus shipped interstate from Florida to reflect historic demand for Florida fresh citrus. Over the last decade, the proportions of Florida fresh citrus shipped within Florida, to other States, and internationally have remained fairly constant. Based on historical data from 1997–98 to 2006–07, an average of 10 percent of Florida's commercially packed fresh citrus was shipped intrastate (within Florida) each season, 52 percent was shipped to other States each season, and 39 percent was exported to other countries each season.

Based on the commenter's estimation of an additional 20 percent of Florida's fresh citrus groves regaining interstate shipment eligibility under this final rule, and given historic distribution patterns, we project as an upper bound that the shipment of fresh citrus to States other than commercial citrus-producing States is likely to be closer to 4.3 million $\frac{4}{5}$ -bushel cartons per season.

Additionally, groves that have been ineligible to produce fruit for interstate movement under the regulations in place before the publication of this final rule have been ineligible due to the presence of citrus canker. It is reasonable to assume that some proportion of the fruit produced in those groves will have visible canker lesions and thus be ineligible for interstate movement, further lowering the potential increase in interstate shipments. Florida fresh citrus shipments are also still subject to the market demand for fresh citrus in States other than commercial citrus-producing States.

The commenter also suggests that the potential increase in revenues could be \$80 million. However, the \$80 million figure assumes that fruit produced from these same groves during past seasons were considered to be unmarketable. Some of that fruit would have been diverted to the processing sector or shipped both intrastate and internationally. The increase in revenue

would have to take the revenue gained by these means into account.

With regard to the second commenter's point, the comparison given is between the incremental benefit to the Florida fresh citrus industry and the total value of the California fresh citrus industry. The commenter did not quantify what costs the commenter expected the California fresh citrus industry to incur as a result of the proposed rule, which is the salient point. We do not expect the regulations promulgated in this final rule to allow the spread of citrus canker to California, and thus we expect the final rule's effect on the California fresh citrus industry to be small as well.

In addition, while the benefits to Florida growers and packers are expected to be small in the short term, the RMA indicates that it will be very hard to certify citrus groves as canker-free in Florida in the future. In the long run, promulgating this rule may be expected to provide additional benefits over the existing regulations, while continuing to prevent the interstate spread of citrus canker.

One commenter, noting that we stated that currently underutilized packing equipment may be utilized for dooryard fruit under the proposed rule, stated that no data are given regarding how much idle capacity exists.

As the volume of fruit moved interstate has declined, approximately 21 citrus packinghouses have shut down in Florida since the 2001–02 season; we do not have data on how many of them could still be used for packing citrus fruit. Our reference to underutilized packing equipment refers mainly to smaller operations, such as gift packers, which are better suited to treating and packing small quantities of citrus. Growers of dooryard fruit who wish to ship their fruit interstate are required to have this citrus treated and inspected under the same provisions required by commercial citrus producers. As such, these growers will turn to facilities equipped to comply with the regulations, such as gift packers. While the cost of shipping citrus under these provisions could be substantial, evidence indicates that dooryard shipments are made purely for the intrinsic value of sharing the fruit with family and friends. As noted earlier in this document, the interstate movement of dooryard citrus from a quarantined area was effectively prohibited under the regulations in place before the publication of this final rule.

Environmental Assessment

We prepared an environmental assessment (EA) documenting the

proposed rule's potential effects on the human environment.

One commenter stated that the EA should examine the potential environmental impacts of the introduction of citrus canker into another commercial citrus-producing State, should APHIS be incorrect in its assessment of the potential for canker to be established in citrus-producing States outside of Florida under the proposed regulations.

Because this final rule prohibits the interstate movement of regulated fruit to commercial citrus-producing States, we do not expect the final rule to result in the introduction or establishment of citrus canker in those States. Therefore, we did not assess the environmental impact that would be associated with such an introduction.

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 shipping season for Florida citrus fruit is in progress. Making this rule effective immediately will allow interested producers and others in the marketing chain to benefit during this year's shipping season. 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. The 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 are amending the citrus canker regulations to modify the conditions under which fruit may be moved interstate from a quarantined area. We are eliminating the requirement that the groves in which the fruit is produced be inspected and found free of citrus canker, and instead requiring that every lot of fruit produced in the quarantined area be inspected by APHIS at a packinghouse operating under a compliance agreement and found to be free of visible symptoms of citrus canker. We are retaining 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. These changes will relieve some restrictions on the interstate movement of fresh citrus fruit from Florida while maintaining conditions that will help prevent the artificial spread of citrus canker.

For this final rule, we have prepared an economic analysis. The analysis, which is summarized below, addresses economic impacts of the proposed new protocol for treatment and inspection of citrus fruit intended for the fresh market. Expected benefits and costs are examined in accordance with Executive Order 12866. Possible impacts on small entities are considered in accordance with the Regulatory Flexibility Act. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 at the beginning of this final rule).

Section 301.75–5 of the regulations lists the designated commercial citrus-producing States as American Samoa, Arizona, California, Florida, Guam, Hawaii, Louisiana, the Northern Mariana Islands, Puerto Rico, Texas, and the U.S. Virgin Islands. Of these 11 commercial citrus-producing States, only 6 States received fresh citrus interstate shipments from Florida during the 2004–05 and 2005–06 seasons: Arizona, California, Louisiana, Puerto Rico, the U.S. Virgin Islands, and Texas. As of August 1, 2006, these 6 States no longer receive fresh citrus shipments from Florida. In this analysis, U.S. commercial citrus-producing States other than Florida are referred to as other commercial citrus-producing States.

The overall objective of this final rule is to continue to prevent the spread of citrus canker to other commercial citrus-producing States, while relieving restrictions on Florida citrus producers, namely, the requirement for interstate movement of citrus fruit that every tree in the grove in which the fruit is grown be inspected, and that the grove be found to be free of citrus canker not more than 30 days before the beginning of harvest. Under the final rule, the citrus fruit will be treated and inspected at the packinghouse prior to interstate movement. Based on the qualitative findings of this economic analysis, we expect the net economic impact of the final rule to be positive.

While citrus produced in Florida is primarily intended for the processed market, citrus produced in California, Texas, Arizona, and Louisiana is largely intended for the fresh market. Approximately 89 percent of Florida citrus production is produced for the juice market, which is not regulated by

the final rule. In contrast, fresh utilization in California accounts for 73 percent of total citrus production. In Texas and Arizona, fresh utilization accounts for approximately 66 and 58 percent of total production, respectively. It is assumed that nearly all Louisiana citrus production is primarily utilized on the fresh market. This final rule continues to prohibit the movement of fresh citrus fruit from Florida to other commercial citrus-producing States. The measures in this final rule are designed to ensure protection of the citrus industries in these States from the introduction of citrus canker and the increased production costs and loss of fresh fruit markets that would result if citrus canker were to be introduced in those States.

Overview of the U.S. Citrus Industry

The total value of U.S. citrus production increased by 16 percent during the 2005–06 season over the previous season from \$2.3 billion to nearly \$2.7 billion. These gains in value reflect increased values for processed utilization for most varieties of citrus in the United States with the exception of grapefruit, which declined in overall value by 4 percent.

Florida is the largest citrus producer in the United States, accounting for approximately 68 percent of U.S. production during the 2005–06 season. California produced approximately 28 percent of the citrus in the United States during the same period, and production in Texas and Arizona comprised the remaining 4 percent. The tumultuous hurricane season of 2004, which included four hurricanes that crossed Florida within a 2-month period, caused significant production losses to Florida's citrus industry and was largely to blame for the 42 percent decline of total utilized production in the United States between the 2003–04 and 2004–05 seasons. Total value of production in Florida citrus fruits showed signs of improvement during the 2005–06 season with a 30 percent increase over the previous season; the increase was largely attributable to higher on-tree prices for both processed and fresh utilization rather than an increase in production.

Evidence suggests a continued trend toward a decline in Florida citrus production. The recent 2006 Commercial Citrus Inventory for Florida reported a 17 percent decline in 2006 over the previous year with the total commercial citrus acreage in Florida at 621,373; the decline is largely attributable to hurricanes, diseases, and urban development. With removals of

citrus trees outnumbering new plantings by a ratio of more than 5:1, there is little indication that production will rebound within the next few years.

The major citrus varieties produced in Florida are early-, mid-, and late-season orange varieties, red and white seedless grapefruit, early tangerines, honey tangerines, temples, and tangelos. Although approximately 89 percent of all Florida citrus is intended for the processed market, the share of production that is processed is highly dependent upon the variety. Approximately 95 percent of all Florida orange production is intended for the processing sector; whereas, nearly 68 percent of Florida tangerine production is utilized on the fresh market. During the 2005–06 season, nearly 36 percent of Florida grapefruit production was utilized on the fresh market. During the previous season, the proportion of Florida grapefruit utilized on the fresh market was approximately 58 percent, suggesting that the post-hurricane higher prices for fresh grapefruit led to a diversion of Florida grapefruit from the processing sector to the fresh market. The reduced rate for fresh market share during the 2005–06 season may suggest a return to a more normal fresh market share of about 40 percent.

The major citrus varieties produced in California are navel and Valencia oranges, grapefruit, tangerines, and lemons. Approximately 73 percent of California citrus was utilized on the fresh market during the 2005–06 season, including nearly 72 percent of California's oranges (making California the largest U.S. producer of fresh-market oranges), 88 percent of the State's grapefruit, 75 percent of its tangerines, and 72 percent of its lemons.

The citrus varieties produced in Texas during the 2005–06 season were grapefruit, Valencia oranges, and midseason oranges. Fresh production accounted for approximately 67 percent of total production. Valencia and midseason orange production was destined primarily for the fresh market, accounting for 79 percent of total production. Also, 62 percent of grapefruit production in that State was utilized on the fresh market.

Arizona produces Valencia and navel oranges, grapefruit, tangerines, and lemons. Approximately 58 percent of Arizona citrus was utilized on the fresh market during the 2005–06 season, including 52 percent of the State's orange production, 65 percent of its tangerine production, 55 percent of its lemon production, and all of its grapefruit production.

Total and domestic shipments of Florida fresh citrus demonstrated a

discernible improvement during the 2006–07 seasons with shipments increasing by 26 percent and 7 percent, respectively, over the previous season. Total and domestic shipments of Florida fresh citrus remained virtually unchanged during the 2005–06 season over the previous season, showing few signs of recovery from the dramatic decline between the 2003–04 and 2004–05 seasons, when total and domestic shipments declined by 42 percent and 29 percent, respectively. Florida total and domestic fresh citrus shipments are 30 percent and 24 percent less, respectively, than they were prior to the 2004–05 season. While fresh grapefruit continues to have the largest share of total shipments of fresh Florida citrus including exports, oranges still account for the State's largest share of domestic shipments. During the 2006–07 season, Florida domestic shipments marginally increased to most geographical U.S. regions, with the noted exception of a 4 percent decline in shipments to the western U.S. region, which was chiefly attributable to the loss of market access to other citrus-producing States.

Expected Costs and Benefits

The changes in the regulations described in this document are likely to primarily affect citrus producers and packinghouses in Florida whose operations rely on the interstate shipment of fresh citrus. The changes will also affect the way resources are allocated for citrus canker mitigation activities at both Federal and State levels.

Effects on Florida Fresh Citrus Shipments

We expect the final rule to have little economic effect on the production of fresh citrus in Florida, but the shift from inspection for citrus canker in the citrus groves, tree by tree, to the inspection of fresh citrus samples at the packinghouse will likely result in increased shipments of fresh citrus to States other than commercial citrus-producing States. As such, the marketing effects of increased quantities of fresh citrus fruit on the domestic market may include changes in fresh market prices, processed market prices, and increased competition. Under this final rule, Florida citrus is still prohibited from distribution to other commercial citrus-producing States.

APHIS expects the quantities of fresh citrus shipped interstate from Florida to reflect historic demand for Florida fresh citrus. We do not expect that interstate shipments of fresh citrus will increase by a proportion equivalent to the potential production for the fresh

market from groves previously prohibited from shipping interstate due to citrus canker. Over the last decade, the proportions of Florida fresh citrus shipped within Florida, to other States, and internationally have remained fairly constant. Based on historical data from 1997–98 to 2006–07, an average of 10 percent of Florida's commercially packed fresh citrus was shipped intrastate (within Florida) each season, 52 percent was shipped to other States each season, and 39 percent was exported to other countries each season.

The average proportion of Florida fresh citrus shipments to the domestic market (intrastate and interstate) over the last decade was approximately 61 percent of total shipments. The average deviation in the proportion of fruit shipped to the domestic market was approximately 3 percent (or approximately 982,000 $\frac{1}{5}$ -bushel cartons).⁸ The proportion of Florida fresh citrus shipments to the domestic market over the last 5 seasons was approximately 62 percent of total shipments, with an average deviation of approximately 5 percent (or roughly 1.2 million $\frac{1}{5}$ -bushel cartons).

Citrus production in Florida has been in decline in recent years due in part to declining citrus tree inventories and harsh weather conditions. Although the total quantity of Florida fresh citrus shipped has declined in recent years, the allocation between the various markets (e.g. interstate, intrastate, and export) has remained fairly consistent despite this downward trend in production. The proportion of Florida fresh citrus shipments to the domestic market prior to the 2004 hurricane season was approximately 60 percent of total shipments, with an average deviation of approximately 2 percent (or approximately 663,000 $\frac{1}{5}$ -bushel cartons each season).

The proportion of Florida fresh citrus shipments to the domestic market for the past three seasons was approximately 65 percent of total shipments, with an average deviation of approximately 4 percent (or approximately 841,000 $\frac{1}{5}$ -bushel cartons each season). The increased variability in the proportion of Florida fresh citrus shipped to the domestic market over the last three seasons is reflective of an industry recovering in the wake of the 2004 and 2005 hurricane seasons. The average quantity of Florida fresh citrus shipped on the

domestic market prior to 2004 was approximately 34.1 million $\frac{1}{5}$ -bushel cartons each season compared to an average of 20.8 million $\frac{1}{5}$ -bushel cartons over the last three seasons.

The Florida Citrus Packers, a nonprofit cooperative association, commented during the public comment period that the spread of citrus canker had resulted in an estimated additional 20 percent of total fresh citrus groves in Florida declared ineligible for interstate shipment under the regulations in place before this final rule because of the presence of citrus canker. The commenter did not report a baseline for this "additional 20 percent." The Florida Citrus Packers further estimated that the fresh citrus fruit produced in these groves represents approximately 8 million cartons of potential business opportunity under the revised regulations. Based on the commenter's estimation of an additional 20 percent of Florida's fresh citrus groves regaining interstate shipment eligibility under this final rule, and given historic distribution patterns, we project as an upper bound that the shipment of fresh citrus to States other than commercial citrus-producing States is likely to be closer to 4.3 million $\frac{1}{5}$ -bushel cartons per season. However, based on the preceding discussion of the small variability in the proportion of fruit shipped to various markets, it is not likely that interstate shipments will increase by this projected upper bound. We also note that a portion of fruit from these groves is expected to fail to meet quality standards for the fresh market and will be diverted to other channels, including the processed market. This issue is discussed in more detail earlier in this document under the heading "Comments on the Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis."

In addition, while any benefits to Florida growers and packers are expected to be small in the short term, the RMA indicates that it will be very hard to certify citrus groves as canker-free in Florida in the future. In the long run, this rule is expected to provide increased benefits in comparison to the regulations in place before the publication of this final rule, while continuing to prevent the interstate spread of citrus canker.

Effects on Consumers

Consumers in States other than commercial citrus-producing States will benefit from any increases in shipments of Florida fresh citrus. The increase in interstate shipments may lead to lower prices, depending on the magnitude of the change and the price elasticity of

⁸ The average deviation is a measure of variability. It is computed for a series of data points by finding the absolute difference between each point and the average (mean) for the series, summing these differences, and dividing by the total number of data points.

demand. If the regulations in place before the publication of this final rule had been maintained, Florida fresh citrus shipments to the domestic market would have been expected to decline, because the number of groves eligible for certification as free of citrus canker would decline as a result of the spread of citrus canker. In the long run, under this final rule, these consumers will benefit from a sustained supply of Florida fresh citrus.

In the short run, consumers within Florida may experience increased supplies associated with rejected lots that have been diverted intrastate. Florida consumers may benefit from near-term price declines, again, depending on the quantities diverted to the fresh market within Florida and the price elasticity of demand. However, in the long run, any increase in intrastate shipments is expected to be less than would occur under the regulations that had been in place before the publication of this final rule. Under those regulations, the number of groves eligible for certification as free of citrus canker would have declined, along with the quantity of fresh citrus approved for interstate movement.

Effects on Florida Packinghouses and Citrus Growers

In terms of operational adjustments, Florida packinghouses are the segment of the citrus industry likely to be the most affected by the change in regulations since the focus of the new protocol for treatments and APHIS inspections will be shifted away from the citrus groves to the packinghouse facilities. The final rule will require citrus packinghouses that move regulated citrus fruit interstate to operate under an APHIS compliance agreement wherein the packinghouse operator agrees to meet all requirements of the regulations. The provisions in § 301.75–7 pertaining to the inspection of groves for citrus canker as a prerequisite for the interstate movement of citrus are being removed.

Citrus producers, however, will still retain the same incentives that currently exist to employ best management practices when producing citrus for the fresh market. A packinghouse charge to the grower for citrus that does not meet the quality requirements is known as an elimination charge, and is an existing industry measure for ensuring high quality, symptom-free fruit. With quality standards in place for fresh citrus, as outlined as part of the U.S.

Standards in the Agricultural Marketing Service's regulations in 7 CFR part 51, growers already employ the practice of surveying for fresh citrus fruit that are not considered of fresh market quality. The high cost of inputs and production practices employed in producing citrus fruit intended for the fresh market yields a relatively low return to citrus growers if the fruit is diverted to the processed market because it is determined to be unsuitable for the fresh market. Production costs associated with citrus fruit intended for the processed market are less than costs associated with citrus fruit produced for the fresh market because the physical appearance of the fruit produced for the processed market is not important; consequently, the value of citrus on the processed market is relatively low compared to the value of citrus sold on the fresh market. In the long run, citrus growers will maintain self-surveys and best management practices as long as the costs of these practices are less than the elimination charges and the price discount that is incurred when their fruit diverted from the fresh to the processed market. Table 2 outlines the average packinghouse charges for Florida fresh citrus during the 2005–06 season.

TABLE 2.—ESTIMATED AVERAGE TOTAL PACKING CHARGES PAID BY GROWERS, AND ELIMINATION CHARGES PAID BY GROWERS FOR LOTS THAT DO NOT MEET QUALITY REQUIREMENTS, 2005–06^a

	Domestic grapefruit	Export grapefruit	Oranges	Temples/ tangelos	Tangerines
	\$/Carton ^c				
Total packing charge ^b	\$4.016	\$4.395	\$4.347	\$4.614	\$5.469
	\$/Box ^c				
Drenching charge	0.181	0.189	0.181	0.184	0.188
Packinghouse elimination charges	0.545	0.553	0.548	0.548	0.552
Hauling charges for eliminations	0.505	0.534	0.515	0.531	0.534

Source: Ronald P. Muraro, University of Florida-Institute of Food and Agricultural Sciences, Citrus Research and Education Center, Lake Alfred, FL, August 2006.

^a These packing charges are based on charges at four citrus packinghouses in the Interior production region and 13 citrus packinghouses in the Indian River production region.

^b Total packing charge refers to the charge to the grower for packed fruit, and is based upon packinghouse operational costs. Total packing charges are discussed in detail in the report "Average Packinghouse Charges for Florida Fresh Citrus—2005–06 Season," (<http://edis.ifas.ufl.edu>).

^c One box is equivalent to two 1/5-bushel cartons.

Focusing regulatory enforcement in the packinghouse via required treatments and inspection of fruit intended for interstate movement is expected to be a more economically efficient means of ensuring a high level of confidence that even a small percentage of infected fruit will be detected than the system in place before the publication of this final rule. Both packinghouses operating under compliance agreements with APHIS and

growers seeking to minimize elimination charges and price discounts have incentives to ensure that only fruit free of visible canker lesions enter a packing facility. Packinghouse operations with fully integrated groves also seek to minimize the costs associated with fruit rejected due to low quality in general, especially since these operations have more control over production practices. (The purpose of the APHIS inspection is to ensure that

fruit is free from visible canker lesions. Packinghouses are responsible for all other quality inspections.) Minimizing the charges back to the grower associated the drenching, elimination, and hauling of fruit unsuitable for the fresh market through the practice of grove surveys is commonly employed by growers as part of their operations. Tree inspections, which were previously conducted by APHIS and the Florida Department of Agriculture and

Consumer Services (FDACS), will, we believe, be conducted as self-surveys by the industry. Given the possibility of elimination charges and price discounts, growers will apply the additional resources needed to conduct these self-surveys as long as the benefits outweigh the costs.

The inspection process will be largely dependent on the physical layout of each particular packinghouse. Conditions that must be met in order for APHIS inspectors to successfully conduct the required inspections would translate into additional costs to the packinghouse. Inspections will either occur at the roll board prior to the fruit being packed or after the fruit is packed. In either case, adequate lighting will be a necessary component for the fruit inspection process. If the inspection occurs after fruit is packed, the packinghouse will be required to provide a table and personnel to repack the boxes after inspection. The APHIS inspection process will be designed with every effort to maintain the efficiency of the packinghouse operation.

If a lot is rejected due to citrus canker detection, the lot will not be approved for interstate movement. Alternative markets for this fruit are the intrastate market, some international markets, or the processed market. The grower or packinghouse will divert the fruit to the market that yields the maximum return. Assuming the fruit is diverted to the intrastate or an international market, the grower may incur repacking charges associated with fruit that was packed before the lot was rejected in boxes or other containers approved only for interstate movement. These charges will likely be in addition to drenching and elimination charges. Since the average price that growers receive on the processed market is less than prices received on the fresh market, growers will likely suffer a loss by diverting rejected lots to the processed market. Growers are more likely to maximize returns by diverting the fruit to available fresh markets, either intrastate or international, depending on demand, even though they will likely incur repacking charges into cartons approved for intrastate or international movement.

Lot size is determined by the packinghouse, and varies according to the size of the packinghouse, the number of packing lines per facility, and the varieties of fresh citrus packed. Additionally, packinghouses generally identify each lot run through the packinghouse with a lot number that can be traced back to the origin of the lot. APHIS field personnel estimate that under ideal circumstances, the

inspection of 1,000 pieces of fruit will take approximately 1 hour and 23 minutes (approximately 5 seconds per fruit). If the lot takes longer than that to run, the inspection is not expected to result in a delay. However, a base inspection level of 1,000 pieces of fruit may delay a lot that would require less time than 1 hour and 23 minutes to run the line. Packing would essentially have to halt while the inspection is completed before the next lot can be run. In addition, if an inspector finds a suspect lesion on a piece of fruit and the packer does not wish to immediately divert to an alternative market (such as the intrastate or foreign market), the movement of that lot will be delayed while APHIS makes a final determination on whether the lesion is a citrus canker lesion.

The time it takes to run a lot of fruit varies by packinghouse, and is determined by numerous factors. It is reasonable to assume that an average time to run a lot of fruit is about 3 hours. On the average, then, the inspection of 1,000 pieces of fruit will not result in delays. If a packinghouse has its own groves and packs its own fruit, lot sizes are generally larger, and no delays should be expected. Packinghouses that do not pack their own fruit tend to run multiple smaller lots whose identity must be maintained to ensure proper payment to the respective growers. These packinghouses are more likely to experience delays caused by the inspection of 1,000 pieces of fruit.

The treatment of fruit with a surface disinfectant, as reflected in the drenching charges in table 1, occurs under the existing regulations and is conducted as a standard practice to extend shelf life. It also is a requirement in the FDACS/Division of Plant Industry (DPI) compliance agreement with packers. Therefore, there is no additional cost associated with the change in regulations.

The APHIS compliance agreements are not expected to present an entirely new situation for the packinghouses. Current compliance agreements with the State of Florida issued by the FDACS/DPI are required of all packinghouses that ship fresh citrus interstate. They require the packinghouses to adhere to inspection requirements prior to the movement of fresh citrus. According to section III.A of the FDACS packinghouse compliance agreement:

Inspection of fruit for citrus canker lesions will take place during the washing/grading process, and a designated number of packed boxes will be required to be pulled, opened and made available for inspection by Federal or State regulatory officials.

(As stated earlier in this document, we intend to provide for sampling of fruit before it is packed into boxes in our compliance agreements with gift packing operations.)

Effects on Public Sector Resources

According to APHIS, 10 additional inspectors will be needed to implement the final rule at a cost of \$450,000 per year. The added cost for increased inspection at the packinghouse is expected to be offset by a reduction in certain operational expenses in other program areas. For example, pre-harvest grove surveys will be reduced to only those required for phytosanitary certification to certain countries. The FDACS anticipates a reduction in field staff by 65 percent from 340 to 120 field staff members, for a cost savings of approximately \$38,000 per inspector (or \$8.4 million). Florida appropriates funds to the FDACS from the Citrus Inspection Trust Fund to pay the costs associated with the salary and benefits of employees of the Bureau of Citrus Inspection.⁹

The State of Florida allocated approximately \$10 million in funds from the Agricultural Emergency Eradication Trust Fund to the Citrus Health Plan line item for the 2007–08 fiscal year to be utilized for grove inspections (generally pre-harvest surveys), regulatory oversight, and nursery surveys. Approximately \$11.3 million in funds from the Agricultural Emergency Eradication Trust Fund were allocated to the Citrus Canker Eradication line item the previous fiscal year, thus reducing emergency eradication program activities by approximately \$1.3 million and allowing for the management of other citrus diseases and pests. Trust funds may be made available upon certification by the Commissioner that an agricultural emergency exists and that funds specifically appropriated for the emergency's purpose are exhausted or insufficient to eliminate the agricultural emergency.¹⁰

The final rule will ensure resource savings associated with inspectors and equipment for the State of Florida of approximately \$9.7 million per annum.

Concluding Statement on Benefits and Costs

Before the publication of this final rule, the regulations for the interstate movement for regulated fruit from quarantined areas placed several

⁹ Title XXXV Section 601.28 of the Florida Statutes.

¹⁰ Title XXXV Section 570.191 of the Florida Statutes.

restrictions on the interstate movement of citrus fruit from Florida, including inspections of citrus groves to ensure that they are free of citrus canker, pre-harvest inspections, treatments, and movement under limited permit.

The new regulations replace the existing protocol for the movement of citrus fruit from citrus canker quarantined areas. A packinghouse that ships fresh citrus interstate is required to operate under an APHIS compliance agreement wherein the packinghouse operator agrees to meet the requirements of the regulations. APHIS inspections of fresh citrus will occur at the packinghouse level. This final rule also specifies treatment requirements for all commercially packed fresh citrus. The required treatment, however, is already performed at the 50 largest commercial packinghouses, as well as at any smaller packinghouses that pack fruit for interstate movement under the regulations in place before the publication of this final rule. We believe packinghouses will adjust to the new regulations with little to no economic hardship in the long run. Packinghouses currently face similar regulations as required by the Florida compliance agreements for packinghouses. Although the final rule adds a definition of *commercial packinghouse* for the purposes of implementing the rule, all currently operating Florida packinghouses qualify as commercial packinghouses under this definition; APHIS thus does not anticipate that commercial citrus packinghouses will incur any costs as a result of adding this new definition.

Packinghouse charges to growers for eliminations and price discounts for fruit diverted from the fresh to the processed market are incentives to growers to ensure fruit sent to the packinghouse for packing is free of symptoms of citrus canker. Growers will self-survey groves as long as the benefits outweigh the cost of the procedure. The provisions will provide the added benefit to growers of being able to ship symptom-free fresh citrus from groves previously prohibited from interstate movement due to the presence of citrus canker in the grove.

The final rule will also provide opportunities for commercial packinghouses to treat and pack interstate shipments of dooryard plantings of citrus fruit. Such shipments will also be inspected by APHIS.

Benefits of this final rule may include the possibility of gains from a larger volume of Florida shipments to consumers in States other than commercial citrus-producing States. Producers would no longer be

prohibited from sending to the packinghouses for interstate shipment fruit from citrus groves in which citrus canker has been detected. As long as a lot of citrus fruit is found to be symptom-free upon APHIS inspection, the lot will be eligible for shipment to States other than commercial citrus-producing States. Growers with citrus groves in which citrus canker has been detected will have an additional marketing option for their fruit. Consumers on the domestic market may benefit from increased market quantities and lower prices of fresh citrus if a greater market demand exists than is met by the current supply. We expect that Florida packinghouses that wish to ship interstate will continue to do so as long as the financial benefits to them of operating under these provisions exceed their costs.

Finally, the costs to the public sector associated with the final regulations are expected to be marginal in comparison to the benefits of a more efficient system for fresh citrus fruit movement.

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires that agencies consider the economic impact of rule changes on small businesses, organizations, and governmental jurisdictions. Section 604 of the Act requires agencies to prepare and make available to the public a final regulatory flexibility analysis (FRFA) describing any changes made to the rule as a result of comments received and the steps the agency has taken to minimize any significant economic impacts on small entities. Section 604(a) of the Act specifies the content of a FRFA. In this section, we address these FRFA requirements.

Need for and Objective of the Rule

Based on our evaluation of production and processing procedures and their impact on removal of citrus canker from the fresh fruit pathway, along with our review of the operational feasibility of enforcing various mitigation measures, APHIS has concluded that the mandatory packinghouse inspection of processed fruit provides an effective safeguard to prevent the spread of citrus canker via the movement of commercial citrus fruit. Since regulations that were in place before the publication of this final rule required groves to be free of citrus canker in order for fruit to be eligible for interstate movement, the changes in this final rule are necessary in order for the packinghouse-based treatment and inspection protocol to be implemented.

Summary of Significant Issues Raised During Comment Period on the Initial Regulatory Flexibility Analysis

There were no significant issues raised in public comment on the initial regulatory flexibility analysis (IRFA) for this rulemaking. One commenter from California, however, expressed concerns that the impact of citrus canker on the production costs in other citrus-producing States would be devastating should the disease spread as a result of this rule. The commenter further defined these costs as the costs involved with copper sprays, isolation fencing, and spraying for disinfection. The commenter went on to declare that monitoring and surveying would be very expensive given the high cost of labor. The majority of citrus producers in California would be considered small entities according to the Small Business Administration (SBA) guidelines.

We have addressed this comment earlier in this document under the heading "Comments on the Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis."

Description and Estimated Number of Small Entities Regulated

Florida's citrus packinghouses and fresh citrus producers comprise the industries that we expect to be directly affected by the final rule. The small business size standards for citrus fruit packing, as identified by the SBA based upon the North American Industry Classification System (NAICS) code 115114 (Postharvest Crop Activities), is \$6.5 million or less in annual receipts. According to the County Business Patterns report for Florida published by the U.S. Census Bureau, there were 71 post-harvest operations in Florida in 2004. Although this publication reports the number of employees, the number of firms by employment size and the annual payroll for firms included in NAICS 115114, it does not report the distribution of annual sales for firms in this category. Neither is information on annual sales published in the Census of Agriculture or the Economic Census. There are at least 142 packinghouses currently registered in Florida.¹¹ While the classification of these establishments by sales volume is not available, it is estimated that approximately 50 of the 142 registered commercial packinghouses are large citrus packinghouses with the remainder being small establishments, many known as gift packers, in Florida. The Fresh Shippers Report, as reported

¹¹ Florida Department of Agriculture and Consumer Services, Division of Fruit & Vegetable Inspection. <http://www.doacs.state.fl.us/fruits>.

by the Citrus Administrative Committee, details quantities of fresh citrus shipments of the top 40 to 50 shippers of each season.¹² At least 98 percent of Florida fresh citrus shipments are packed through the top 40 to 50 packinghouses in the State.¹³ During the 2005–06 citrus season, annual sales for 21 of the top 40 shippers (52.5 percent) were below the SBA size standard of \$6.5 million. It is estimated that at least 85 percent of citrus packers, including small gift packers, are considered small according to the SBA size standards.

The final rule will implement a new protocol for inspections and treatments that will likely result in additional costs to packinghouses. Examples of additional costs include providing adequate lighting and space for fruit inspection and labor to repack boxes which have been unpacked during inspection. Essentially, the inspection and treatment process is an additional quality control measure. In the short run, it is likely that commercial packinghouses will increase packing charges to cover any additional costs associated with the final rule, passing some of the cost of the rule onto the growers. However, packinghouse average costs may rise with the imposition of this quality control measure due to increases in the average variable costs associated with maintaining a consistent level of output. Examples of expected increases in average variable costs include higher labor costs associated with repacking of 4/5-bushel cartons or an inspection process that slows or shuts down the packing line for any period of time. The inspection process will add one more layer to the production process. As the base level for inspection increases, so does inspection time. Therefore, as inspection sample size increases, the efficiency and productivity of the packinghouse, especially the smaller packinghouses and gift packers, could become hindered. Overall, the industry will benefit; inspection for citrus canker lesions at the packinghouse will maintain sales to interstate markets more efficiently than would be possible under the current grove inspections.

The final rule will also affect producers of fresh citrus in Florida. Most, if not all, of the Florida citrus producers that will be affected by the final rule are small, based on 2002 Census of Agriculture data and SBA guidelines for entities classified within

the farm categories Orange Groves (NAICS 111310) and Citrus (except Orange) Groves (NAICS 111320). SBA classifies producers in these categories with total annual sales of not more than \$750,000 as small entities. According to 2002 Census data, there were a total of 7,653 citrus farms in Florida in 2002. Of this number, approximately 94 percent had annual sales in 2002 of less than \$500,000, which is well below the SBA's small entity threshold of \$750,000.¹⁴ While it is likely this final rule will result in higher packinghouse charges to the grower, costs associated with the final rule are expected to be minimal. Citrus growers previously prohibited from interstate shipment of fresh citrus due to citrus canker detection in their groves will have an additional marketing opportunity for their fruit provided the fruit meets the requirements to pass APHIS inspection.

Description and Estimate of Compliance Requirements

Florida's packinghouses that ship fresh citrus interstate would be subject to compliance agreements with APHIS, as described in section IV of the full final regulatory impact analysis.

Description of Steps Taken To Minimize Significant Economic Impacts on Small Entities

APHIS does not believe small entities will suffer significant economic losses as a result of this final rule. APHIS intends to devise a compliance agreement that is suitable for both large and small commercial packinghouses, especially with respect to the inspection process. Citrus growers will continue to have the same incentives to employ best management practices that will yield citrus fruit meeting the quality standards required at the packinghouse.

Executive Order 12372

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

Executive Order 12988

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

¹⁴ Source: SBA and 2002 Census of Agriculture.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the interstate movement of citrus fruit under the conditions specified in this rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the Regulations.gov Web site.¹⁵ Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, Room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0325.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to

¹⁵ Go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0022>. The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

¹² "Fresh Shippers Report: 2005–06 Season Through July 31, 2006," Citrus Administrative Committee, August 18, 2006. <http://www.citrusadministrativecommittee.org/>.

¹³ *Ibid.*

provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

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List of Subjects

7 CFR Part 301

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

7 CFR Part 305

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

■ Accordingly, we are amending 7 CFR parts 301 and 305 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. Section 301.75-1 is amended as follows:

■ a. In the definitions for "*certificate*" and "*limited permit*", by adding the words "stamp, form, or other" after the words "An official".

■ b. By adding new definitions of "*commercial packinghouse*" and "*lot*" to read as set forth below.

§ 301.75-1 Definitions.

* * * * *

Commercial packinghouse. An establishment in which space and equipment are maintained for the primary purpose of packing citrus fruit for commercial sale. 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.

* * * * *

Lot. The inspectional unit for fruit composed of a single variety of fruit that has passed through the entire packing process in a single continuous run not to exceed a single workday (i.e., a run started one day and completed the next is considered two lots).

* * * * *

■ 3. Section 301.75-7 is amended as follows:

■ a. Paragraphs (a)(1), (a)(2), (a)(5), and (a)(6) are revised to read as set forth below.

■ b. An OMB citation is added at the end of the section to read as set forth below.

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

(a) * * *

(1) Every lot of regulated fruit to be moved interstate must be inspected by an 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.¹

(2) 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.

* * * * *

¹ If conditions warrant changing the number of fruit to a quantity that gives a statistically significant level of confidence of detecting lots containing a different percentage, determined by the Administrator, of fruit with visible canker lesions, APHIS will provide for public participation in that process through the publication of a notice in the **Federal Register**.

(5)(i) 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 the statement “Limited Permit: USDA–APHIS–PPQ. Not for distribution in AZ, CA, HI, LA, TX, and American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands of the United States.” Only fruit that meets all of the requirements of this section may be packed in boxes or other containers that are marked with this statement;

(ii) *Provided*, that until August 1, 2008, fruit that meets all the requirements of this section may be packed in bags that are clearly marked with the statement “Not for distribution in AZ, CA, HI, LA, TX, and American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands of the United States,” as long as the bags of fruit are packed in boxes that are marked as required by paragraph (a)(5)(i) of this section. Fruit that does not meet all the requirements of this section may not be packed in either bags

or boxes that are marked with this statement.
(6) A lot of fruit that is determined to be ineligible for interstate movement under paragraph (a)(1) of this section may not be reconditioned and submitted for reinspection.

- * * * * *
- (Approved by the Office of Management and Budget under control number 0579–0325)
- 4. Section 301.75–11 is amended as follows:
- a. In paragraph (a), by revising the introductory text to read as set forth below.
- b. By redesignating paragraph (a)(3) as paragraph (a)(4) and adding a new paragraph (a)(3) to read as set out below.
- c. In newly redesignated paragraph (a)(4) by adding the words “, peroxyacetic acid,” after the word “hypochlorite”.
- d. In paragraph (d)(3), by removing the word “or”.
- e. In paragraph (d)(4), by removing the period at the end of the paragraph and adding the word “; or” in its place.
- f. By adding a new paragraph (d)(5) to read as set forth below.

§ 301.75–11 Treatments.
(a) *Regulated fruit.* Regulated fruit for which treatment is required by this subpart must be treated in at least one of the following ways at a commercial packinghouse whose owner operates under a compliance agreement under § 301.75–7(a)(2):

* * * * *

- (3) *Peroxyacetic acid.* The regulated fruit must be thoroughly wetted for at least 1 minute with a solution containing 85 parts per million peroxyacetic acid.
- * * * * *
- (d) * * *
- (5) A solution containing 85 parts per million peroxyacetic acid (indoor use only).

PART 305—PHYTOSANITARY TREATMENTS

- 5. The authority citation for part 305 continues to read as follows:
- Authority:** 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.
- 6. Section 305.11 is amended by adding a new paragraph (c) to read as follows:

§ 305.11 Miscellaneous chemical treatments.

* * * * *

- (c) *CC3 for citrus canker.* The fruit must be thoroughly wetted for at least 1 minute with a solution containing 85 parts per million peroxyacetic acid.
- Done in Washington, DC, this 14th day of November 2007.
- J. Burton Eller,**
Acting Under Secretary for Marketing and Regulatory Programs.
[FR Doc. E7–22549 Filed 11–16–07; 8:45 am]
- BILLING CODE 3410–34–P**