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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS-2009-0023]

RIN 0579-AC96

Citrus Canker; Movement of Fruit From Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: 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 each lot of finished fruit be inspected at the packinghouse and found to be free of visible symptoms of citrus canker and removing the current prohibition on the movement of fruit from a quarantined area to commercial citrus-producing States. We are continuing to require fruit moved interstate from a quarantined area to be treated with an approved disinfectant and to be packed in a commercial packinghouse that operates under a compliance agreement. These changes will relieve some restrictions on the interstate movement of fresh citrus fruit from quarantined areas while maintaining conditions that will prevent the artificial spread of citrus canker.

EFFECTIVE DATE: October 22, 2009.

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

SUPPLEMENTARY INFORMATION:

Background

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

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

On June 30, 2009, we published in the **Federal Register** (74 FR 31201-31209, Docket No. APHIS-2009-0023) a proposal[1] to amend the regulations to modify the conditions under which fruit may be moved interstate from a quarantined area. We proposed to eliminate the requirement that each lot of finished fruit be inspected at the packinghouse and found to be free of visible symptoms of citrus canker and to remove the current prohibition on the movement of fruit from a quarantined area to American Samoa, Arizona, California, Guam, Hawaii, Louisiana, Commonwealth of the Northern Mariana Islands, Puerto Rico, Texas, and the U.S. Virgin Islands. (These are the commercial citrus-producing areas listed in § 301.75-5; we refer to them in this document as commercial citrus-producing States.)

We proposed to continue to require fruit moved interstate from a quarantined area to be treated with an approved disinfectant and to be packed in a commercial packinghouse that operates under a compliance agreement. We proposed these changes to relieve some restrictions on the interstate movement of fresh citrus fruit from quarantined areas while maintaining conditions that would prevent the artificial spread of citrus canker.

We solicited comments concerning our proposal for 60 days ending August 31, 2009. We received 34 comments by that date. They were from citrus producers, citrus packers, industry organizations, researchers, and representatives of State and foreign governments. Twenty-three commenters supported the proposed rule. Two of these commenters also directly addressed issues raised in the remaining comments, which are discussed below by topic.

Selection of an Option for Mitigating the Risk Associated With the Interstate Movement of Regulated Fruit From a Quarantined Area

In a final rule[2] effective and published in the **Federal Register** on November 19, 2007 (72 FR 65172-65204, Docket No. APHIS-2007-0022), we amended the regulations to establish new conditions for the interstate movement of regulated fruit from an area quarantined for citrus canker. That final rule eliminated a requirement that the groves in which fruit to be moved interstate is produced be inspected and found free of citrus canker. Instead, we added the packinghouse inspection requirement mentioned earlier. We retained the other requirements that had been in the regulations, including the requirement that the fruit be treated with a surface disinfectant and the prohibition on the movement of fruit from a quarantined area into commercial citrus-producing States.

We established those conditions based on the conclusions of a pest risk assessment (PRA) and risk management analysis (RMA) prepared for the 2007 rulemaking. The PRA concluded that asymptomatic, commercially produced citrus fruit, treated with a disinfectant and subject to other mitigations, is not epidemiologically significant as a

[1] To view the proposed rule and the comments we received, go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0023*).

[2] To view the November 2007 final rule, go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0022*).

pathway for the introduction and spread of citrus canker.

The RMA examined the risks associated with both symptomatic and asymptomatic fruit and concluded that the introduction and spread of Xcc into other States through the movement of commercially packed fresh citrus fruit from quarantined areas is unlikely. In addition, the RMA concluded that a phytosanitary inspection would ensure, with high confidence, that few shipped fruit would have symptoms of citrus canker disease. However, the RMA also concluded that the evidence available at that time was not sufficient to support a determination that fresh citrus fruit produced in an Xcc-infested grove cannot serve as a pathway for the introduction of Xcc into new areas, thus necessitating the prohibition on movement of fruit into commercial citrus-producing States.

In our responses to public comments in the Background section of the November 2007 final rule, we stated: ''If, in the future, evidence is developed to support a determination that commercially packed citrus fruit (both symptomatic and asymptomatic) is not an epidemiologically significant[3] pathway for the introduction and spread of citrus canker, we would undertake rulemaking to amend our regulations accordingly.''

Since the publication of the November 2007 final rule, two publications have provided additional evidence regarding the potential of fruit to serve as a pathway for the introduction and spread of citrus canker. This new evidence addresses key uncertainties and caused us to revisit our previous findings. The first article, by Gottwald *et al.* (2009), documents research on the survival of Xcc on commercially produced and packed citrus fruit and the likelihood that such fruit could serve as a mechanism to spread the disease. The second article, by Shiotani *et al.* (2009), documents research on the survival of Xcc on commercially produced mandarin fruits and the likelihood of spread of Xcc to trees from harvested mandarins.

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

These conclusions led us to prepare a supplemental RMA, titled ''Movement of Commercially Packed Citrus Fruit from Citrus Canker Disease Quarantine Area; Supplemental Risk Management Analysis'' (May 2009). The supplemental RMA takes into account the conclusions of the updated PRA as well as the evidence and discussion presented in the November 2007 RMA. Like the November 2007 RMA, the supplemental RMA was submitted for peer review, in accordance with the Office of Management and Budget's bulletin on peer review. All the materials associated with the peer review on the supplemental RMA, including the peer reviewers' comments and our responses, are available at (*http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml*). The peer reviewers' comments were considered in developing the supplemental RMA.

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

- Disease management practices in the grove reduce, but do not eliminate, Xcc populations.
- Commercially produced fruit harvested in areas where Xcc exists may be visibly infected or the fruit may carry the pathogen either on its surface or in wounds.
- Citrus canker disease development between harvest and packinghouse, via wounding for example, is not likely.
- Procedures for cleaning and disinfecting fruit are routinely applied by packinghouses.
- The individual efficacy of these procedures for removing or destroying Xcc may not be known in detail, but the effect of packinghouse treatments reduces the prevalence of viable Xcc and therefore the level of inoculum associated with commercially packed fresh citrus fruit.
- Packinghouse processing that includes a disinfectant treatment further reduces amounts of Xcc inoculum on infected or contaminated fruit.
- The viability of bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested.
- The viability of Xcc bacteria that survive the packing process will further diminish during shipping.
- Epiphytic populations of Xcc may aid in pathogen dispersal, but substantial evidence indicates that bacterial populations do not infect intact mature fruit.
- Evidence indicates that wounds on harvested fruit containing Xcc inoculum do not lead to citrus canker lesion development, and Xcc populations generally decline rapidly, although wounds might occasionally retain Xcc populations that decline more slowly.
- The cool temperatures at which citrus fruit are stored and shipped and the duration of storage reduce the ability of Xcc to reproduce and cause infection.
- As a condition for successful establishment, Xcc, in amounts sufficient to cause infection, must encounter not only an environment with a conducive temperature, relative humidity, moisture, and wind events for infection, but also must encounter host plant tissue that is either at a susceptible growth stage or is wounded and then must successfully enter this tissue.
- Despite substantial international trade between Xcc-infested and noninfected countries, there is no authenticated record of movement of diseased fruit or seeds resulting in the introduction of Xcc to new areas.

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

- *Option 1:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, without packinghouse treatment with a disinfectant.
- *Option 2:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, subject to packinghouse treatment with an Animal and Plant Health Inspection Service (APHIS)-approved disinfectant,

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

but without the current inspection requirement.

- *Option 3:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States except commercial citrus-producing States, subject to packinghouse treatment of citrus fruit with an APHIS-approved disinfectant treatment; and, allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, including commercial citrus-producing States, subject to packinghouse treatment with an APHIS-approved disinfectant treatment and APHIS inspection for symptoms of citrus canker.
- *Option 4:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States other than commercial citrus-producing States, subject to packinghouse treatment with an APHIS-approved disinfectant.
- *Option 5:* Leave the current regulations for the interstate movement of citrus fruit from areas quarantined for citrus canker unchanged.

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

Several commenters acknowledged that the risk associated with the interstate movement of regulated fruit from a quarantined area is low but stated that, if there is any risk associated with allowing fruit to move from areas quarantined for citrus canker into commercial citrus-producing States, such movement should be prohibited. These commenters stated that citrus canker has been a destructive and costly disease in Florida, one which spurred an eradication attempt that was ultimately unsuccessful, and that other commercial citrus-producing States do not want to be at risk for the introduction and establishment of the disease. One commenter recommended that we err on the side of caution in making changes to the regulations and stated that further research should be done before fruit from quarantined areas is allowed into commercial citrus-producing States.

Two of these commenters proposed additional risk mitigation measures to address the risk they perceived to be associated with fruit moved interstate from an area quarantined for citrus canker. Both stated that such fruit should not be allowed to move into the eight-county Citrus Zone in south Texas. These commenters cited the suitability of Texas' climate to citrus canker establishment (as demonstrated by previous outbreaks of citrus canker in Texas), the susceptibility of grapefruit (a common citrus crop in Texas) to citrus canker, and citrus canker's effect on young citrus trees. One of these commenters additionally requested that fruit destined for Texas originate only from groves that have been certified as being free of citrus canker for more than a year, based on a survey.

Another commenter, responding to some of these commenters, stated that no agricultural trade between States and countries anywhere in the world could be conducted if minimal risk is unacceptable and that the proposed rule would mitigate the risks to the point that risks are negligible.

Our goal in restricting the interstate movement of plants, plant products, and other articles is not to achieve zero risk, which, as the last commenter noted, cannot be achieved in agricultural trade. Rather, we seek to impose restrictions on the interstate movement of such articles that are commensurate with the risk they pose and that mitigate the risk associated with their interstate movement. Based on all the available scientific evidence, the updated PRA and supplemental RMA concluded that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc. We received several comments on the two new publications that led us to prepare the updated PRA and supplemental RMA, as well as comments on the updated PRA and supplemental RMA themselves. These comments are discussed in further detail later in this document. However, they did not change our conclusion that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the spread of Xcc. Accordingly, this final rule implements Option 2 as proposed.

We are not retaining the current prohibition on the distribution of fruit from a quarantined area to commercial citrus-producing States, and we are not adding the additional mitigations requested by two of the commenters. Based on our determination that fruit is not an epidemiologically significant pathway, we have determined that those additional mitigations are unnecessary to prevent the spread of citrus canker via the interstate movement of fruit from quarantined areas. As noted, it is impossible to eliminate all risk associated with the interstate movement of fruit from quarantined areas; given the conclusions of the updated PRA and the supplemental RMA, following the recommendation that we prohibit the movement of fruit into commercial citrus-producing States unless all risk is eliminated would impose an unnecessary restriction on the movement of fruit.

Under section 412(a) of the Plant Protection Act (7 U.S.C. § 7712), the Secretary of Agriculture may prohibit or restrict the interstate movement of any plant or plant product if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination within the United States of a plant pest or noxious weed. Based on our supplemental RMA, APHIS has concluded that commercially packed citrus fruit treated with an APHIS-approved disinfectant is not an epidemiologically significant pathway for the dissemination of citrus canker within the United States. Accordingly, APHIS has determined that it is not necessary to prohibit the interstate movement of regulated fruit that is commercially packed and treated with an APHIS-approved disinfectant from an area that is quarantined for citrus canker in order to prevent the dissemination within the United States of a plant pest. This determination is based on the findings of the updated PRA and the supplemental RMA referred to earlier in this document and our judgment that the application of the measures we proposed will prevent the dissemination of plant pests within the United States.

One commenter who was opposed to allowing the interstate movement of citrus fruit from a quarantined area to commercial citrus-producing States stated that California, a commercial citrus-producing State, is the home of three of the most important resources of citrus germplasm in the United States: The National Clonal Germplasm Repository for Citrus and Dates (NCGRCD), a U.S. Department of Agriculture-Agricultural Research Service (ARS) facility supplying budwood worldwide; the Citrus Clonal Protection Program, University of California-Riverside (UCR), the first citrus germplasm program in the world supplying budwood to California, Arizona, and Texas; and the UCR Citrus Variety Collection, perhaps the most diverse citrus collection in the world dating back to 1907. The commenter stated that certified disease-free budwood and a broad genetic basis for

variety development and improvement are the foundation of every successful, profitable, and sustainable citrus industry in the world and that those three germplasm resources are the only ones in the United States (if not the world) that have not been exposed to citrus canker or other devastating citrus diseases such as citrus greening. The commenter stated that taking a ''calculated'' risk to expose these invaluable resources to one of the worst citrus diseases in the world, citrus canker, based on limited field and packinghouse practices that will not be inspected for compliance is unacceptable. This commenter also stated that the Florida citrus industry funded a project to ''rescue'' Florida citrus germplasm by moving it to citrus canker- and citrus greening-free California in the NCGRCD facilities.

As we have determined that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of citrus canker, we do not expect that these facilities will be exposed to citrus canker as a result of the implementation of this final rule.

However, it should be noted that germplasm facilities are devoted to the preservation of the germplasm within the facilities and thus are protected against potential sources of pest and disease introduction. Indeed, potentially infected germplasm from foreign countries is imported into these same facilities for screening purposes, which is a much more likely pathway for the introduction of diseases such as citrus canker than the interstate movement of regulated fruit from a quarantined area. Allowing citrus fruit to be moved interstate from quarantined areas into California will not decrease the efficacy of the biosecurity in place at these facilities.

It should also be noted that, under this final rule, packinghouses will be inspected to ensure that they are complying with the requirements to treat regulated fruit with an APHIS-approved disinfectant and to ensure that the fruit is free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit. With regard to the other commercial fruit production practices described in the November 2007 RMA, we assume that commercial growers and packinghouses will continue to employ procedures that reduce the incidence of citrus canker in their fruit, as citrus canker lesions reduce the market value of infected fruit.

New Evidence We Considered in the Updated PRA and Supplemental RMA

Several commenters generally addressed the Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications. We address these comments below.

One commenter stated that the premise of both publications was to prove that citrus canker cannot be transmitted by infected or contaminated citrus fruit. The commenter stated that, scientifically, a negative premise cannot be proven, and the commenter cited this as one major flaw of these studies. Another commenter stated that Shiotani *et al.* (2009) did not demonstrate that Xcc cannot be transmitted from fruit to susceptible tissue, as it did not adequately resolve the ability of Xcc to spread from asymptomatic fruit.

One commenter, responding to the first commenter, stated that the two publications never set out to prove that something cannot happen because, philosophically and scientifically, this is impossible. However, the commenter stated, both publications soundly proclaim that risks can very effectively, very simply, and very reliably be reduced below any reasonable and measurable risk of transmitting citrus canker disease.

As the last commenter states, neither of the publications concluded that citrus canker cannot be spread by fruit. Gottwald *et al.* (2009) concluded that ''harvested and packinghouse-disinfested citrus fruit are extremely unlikely to be a pathway for Xcc to reach and infect susceptible citrus and become established in canker-free areas.'' Shiotani *et al.* (2009) concluded that ''there is a low risk [of] transmission'' of Xcc from fruit. These conclusions are consistent with the conclusions of the updated PRA and supplemental RMA, as described earlier.

Two commenters stated that the research in the Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications should be tested and retested by others who were not involved in the original research before changing the conditions under which fruit is allowed to move from an area quarantined for citrus canker. Three commenters stated that a national task force consisting of scientists from citrus-producing areas other than Florida (and besides ARS personnel) should be assembled to address any change in current quarantine regulations that might result in the introduction of known destructive pathogens from known infected areas to noninfected areas (*i.e.*, California, Arizona, Texas, etc.).

The Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications were produced independently, published in a peer-reviewed journal, and came to similar conclusions regarding the epidemiological significance of fruit as a pathway for the spread of citrus canker. Among other topics they address, these publications provide valuable evidence regarding the potential for Xcc to spread from infected fruit to host plants in the field; this evidence is what prompted us to prepare the updated PRA and supplemental RMA.

However, the updated PRA and supplemental RMA considered all the available evidence regarding the potential of fruit to serve as an epidemiologically significant pathway for the introduction and spread of citrus canker, not just the evidence in those publications. The weight of all the available evidence is what led us to the conclusion that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc. We have determined that the evidence provides adequate certainty regarding this conclusion to remove some restrictions on the interstate movement of commercially packed and disinfected fresh citrus fruit from an area quarantined for citrus canker.

The November 2007 PRA and RMA and the supplemental RMA prepared for this rulemaking were all submitted for peer review in accordance with the Office of Management and Budget's bulletin on peer review. The peer reviewers for the November 2007 PRA and RMA and the supplemental RMA were experts in plant pathology, phytobacteriology, and risk assessment. The comments we received from these peer reviewers indicated that our analysis of the available evidence regarding the risk associated with the movement of fruit from an area quarantined for citrus canker was sound.

It should also be noted that the authors of the Shiotani *et al.* (2009) publication were not affiliated with the State of Florida in any way, and the experiments in the Gottwald *et al.* (2009) publication were conducted by an international consortium of scientists working cooperatively and reaching the same conclusion after conducting similar experiments in two different countries, with participants from Argentina as well as Florida.

Gottwald et al. (2009)

We received several comments specifically addressing Gottwald *et al.* (2009).

Some of the experiments included in Gottwald *et al.* (2009) examined the

effectiveness of treatment with a disinfectant at reducing Xcc populations on citrus fruit. One commenter stated that the disinfection procedures significantly reduced pathogen survival but did not completely eliminate it. The commenter stated that, considering the large amount of fruit being shipped, even a low survival rate of the pathogen poses a high risk for the introduction of Xcc to a disease-free area.

This commenter also stated that the limitation of treatments in disinfecting fruit with lesions or fruit wounds contaminated with inoculum of the pathogen is well known. Oxidizing agents cannot effectively remove or reduce inoculum to acceptable levels in wounded tissue because of the natural reducing agents that occur in fruit tissue. Furthermore, these treatments would have little or no effect on established fruit lesions that act as reservoirs of inoculum. Thus, the commenter stated, without any inspections, even a few lesions on fruit would pose a high risk because the pathogen could not be eliminated using existing disinfection practices.

Another commenter stated that one cannot in a practical sense sterilize the surface of fruit; it would do more harm than good, and there is no biological reason to do so. The commenter stated that there is an inoculum threshold necessary to naturally establish citrus canker under even the most conducive conditions (10^5 colony-forming units (cfu)/milliliter (ml) for intact tissue infection, 10^3 cfu/ml for wounded) and that fruit disinfection easily achieves the low levels of inoculum necessary to avoid the risk of disease transmission. The commenter stated that the concern that inoculum in wounds on fruit could not be completely eliminated overlooks the fact that the bacteria do not even cause an infection at the wound site, let alone become liberated to possibly induce a lesion elsewhere.

The November 2007 RMA and the supplemental RMA both acknowledge the fact that disinfection treatments are not completely effective against Xcc bacteria in lesions. However, as the November 2007 RMA stated, there is abundant evidence that shows that packinghouse disinfection treatments destroy surface bacteria and reduce the viability of all bacteria on fruit. We did not rely solely on the Gottwald *et al.* (2009) publication in making our determination that treatment with an APHIS-approved disinfectant is an effective mitigation against the risk of spread of citrus canker; rather, we considered all the available evidence regarding the effectiveness of disinfectant treatments.

In addition, other evidence indicates that bacteria that remain in lesions after disinfection are not epidemiologically significant. For example, Gottwald *et al.* (2009) provided additional evidence supporting the conclusion that the viability of bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested and that the viability of Xcc bacteria which survive the packing process will further diminish during shipping.

We disagree with the first commenter that the effectiveness of disinfectant treatment on bacteria in wounds is a concern. The second commenter is correct to note that Xcc bacteria in wounds do not cause infections at the wound site. As discussed in the supplemental RMA, evidence indicates that wounds on harvested fruit containing Xcc inoculum do not lead to citrus canker lesion development, and Xcc populations generally decline, although wounds might occasionally retain Xcc populations that decline more slowly.

Finally, with respect to the first commenter's concern about elimination of bacteria, we acknowledge that the surface disinfectant treatments approved by APHIS reduce numbers of Xcc cells to low or undetectable levels, but do not necessarily provide complete eradication. As the second commenter notes, complete eradication would be impractical. In any case, it is not necessary to completely eradicate Xcc in order to ensure that disinfected fruit is not an epidemiologically significant pathway. While the updated PRA and supplemental RMA conclude specifically that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc, it is not just the disinfection process that makes fruit not an epidemiologically significant pathway for Xcc, but also the biology of Xcc and the conditions that must be fulfilled in order for Xcc transmission from infected fruit to a host plant to occur, among other factors.

Some commenters addressed experiments in the Gottwald *et al.* (2009) publication that were designed to investigate the likelihood that citrus fruit disposed of by consumers may serve as a source of inoculum for nearby host material. Gottwald *et al.* (2009) studied the transmission of Xcc from unprocessed, infected 'Ruby Red' grapefruit and 'Lisbon' lemon and packinghouse-processed 'Ruby Red' grapefruit in cull piles to 'Duncan' grapefruit seedlings during natural weather events. During the course of the experiments, citrus canker lesions did not develop on the grapefruit seedlings (488 seedlings total) surrounding the diseased fruit, in spite of extensive leafminer damage present on some of the seedlings. Xcc bacteria were not detected in assays of the foliage.

Gottwald *et al.* (2009) repeated the cull pile experiment to see if transmission of Xcc from infected, unprocessed 'Ruby Red' grapefruit fruit is possible under simulated extreme wind and rain conditions. Infected fruit were either placed in a cull pile or suspended by vertical strings. One seedling 0 meters (m) downwind from the cull pile became infected when subjected to the highest wind speed (25 m per second (m/s)) and simulated rain, developing 1 lesion on a single leaf injured by the action of the high-speed fan. The other 191 plants in the study did not develop Xcc lesions. No Xcc lesions developed on the 192 plants placed at the same distance and subjected to the same wind speed (0, 10, and 25 m/s with water) from Xcc-infected grapefruit suspended from string. Xcc was recovered from 1 collection screen set up 2 m from suspended fruit, but no Xcc was recovered from the other 144 collection screens set up at various distances (0 to 10 m) from cull piles or suspended fruit. Gottwald *et al.* (2009) stated that this cull pile experiment was ''a highly contrived situation designed to provide every possible opportunity for dispersal of Xcc and would be unlikely to occur in most areas, except those locations where hurricanes or tropical storms are common occurrences.''

One commenter noted that one plant surrounding infected fruit in cull piles did develop the disease in one of the simulated wind and rain experiments, indicating that this pathway of transmission is possible. The commenter stated that one might think that this level of transmission from an infected fruit to a healthy plant is very low, but this can be interpreted as very high under the set of conditions established for the experiments. The commenter stated that conducting these studies in regions where other environmental conditions exist and with a different group of scientists may lead to a different conclusion.

A second commenter stated that both Gottwald *et al.* (2009) and Shiotani *et al.* (2009) demonstrate that transmission of the bacterium is a difficult process to replicate and expressed a view that the natural spread of the bacterium from infected fruit to host plants remains poorly understood. The commenter stated that the cull pile transmission experiments conducted by Gottwald *et al.* (2009) do not provide conclusive

evidence that the risk of fruit-to-tree transmission is insignificant. The commenter stated that these trials were conducted with little replication and did not adequately represent weather events that are conducive to the transmission of the bacterium, that the authors did not demonstrate that Xcc could initiate infections under the experimental conditions in positive controls, and that the employed diagnostic methods were not tested in positive controls.

This commenter also noted that transmission of Xcc from infected fruit to host plants did occur, despite each wind speed treatment being applied for only 5 minutes. While APHIS concluded that the experimental conditions that produced this result were ''highly contrived,'' the commenter stated, due to the small-scale nature of this trial, small sample sizes, short exposure times, and lack of adequate controls, the risk of transmission under natural conditions remains feasible and significant. The commenter concluded that the experiments by Gottwald *et al.* (2009) demonstrated the ability of Xcc to be spread from symptomatic citrus fruit.

A third commenter stated that the transmission of Xcc from infected fruit to host plants in the simulated extreme wind and rain conditions was probably because of mechanical contact and injury, not from anything most people would consider as a natural transmission event. This commenter also noted that the cull pile in that experiment was composed of freshly picked and heavily infected fruit, not fruit that had been graded and disinfected according to packinghouse protocol. The commenter stated that the value of this experiment is that it demonstrates the ''tipping point'' for canker infection from fruit. The commenter stated that if the other commenters envision a pile of freshly picked canker-infected grapefruit suddenly arriving in a grapefruit orchard in Australia, Arizona, or California immediately adjacent to susceptible plants and experiencing 25 m/s winds accompanied by rain, the scenario is excessively imaginary. The ''tipping point,'' in this commenter's view, identifies the dangerous conditions for shipping fresh fruit from a canker endemic area so they can be completely avoided.

We agree with the first two commenters that it would have been optimal to have additional replications of the experiment in which Xcc was transmitted from infected fruit to host plants, to better determine the rate at which transmission occurs in these conditions. However, as noted, the conditions in the experiment in which Xcc was successfully transmitted from infected fruit to host plants were extreme conditions, designed (as the third commenter states) to establish whether transmission of Xcc from infected fruit to host plants is possible, not whether it is likely. (As the third commenter notes, Gottwald *et al.* (2009) concluded that the lesion that resulted from the simulated wind and rain cull pile experiment ''was the result of a leaf wound.'')

In the context of the other experiments Gottwald *et al.* (2009) performed to assess the likelihood of fruit-to-plant transmission, and in the context of the conditions of the experiment, including not only the simulated extreme wind and rain conditions but also the fact that the fruit were unprocessed and untreated and the placement of those fruit directly adjacent to host plants, we have determined that this one successful transmission is consistent with a determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc, given all the available evidence about the potential for fruit to serve as a pathway.

Although the first commenter is correct that conducting the experiments in other environmental conditions and with another group of scientists might lead to a different conclusion, based on the available science regarding the transmission of citrus canker, the environmental conditions under which these experiments were conducted are extremely suitable to the potential transmission of citrus canker. Fruit that were specifically selected for their high level of infection and that were subjected to none of the packinghouse processes (including disinfection) that are known to reduce the viability of Xcc infection were used in attempts to infect highly susceptible grapefruit plants at the most susceptible stage of the plants'development. The one trap plant that was infected was placed immediately adjacent to the infected fruit and subjected to simulated extreme wind and rain conditions that are unlikely to occur in most areas. We have determined that it is unlikely that studies in other regions and under other environmental conditions would produce a greater level of transmission of the disease from infected fruit to host plants.

We have determined that the Gottwald *et al.* (2009) experiments adequately represented weather events that are conducive to the transmission of Xcc and represented a range of weather conditions as well. The trials were conducted both in field conditions that were not conducive to the transmission of Xcc, in Argentina, and that were conducive, in Florida.

It would be difficult to develop a positive control for the cull pile experiments, as a positive control would require the successful transmission of Xcc, which Gottwald *et al.* (2009) were only able to accomplish under conditions described in the publication as ''highly contrived.'' (It should be noted that this was not APHIS' description.) Nevertheless, it should be noted that the authors who performed the cull pile experiments have performed similar experiments using yard blowers, as documented in Bock *et al.* (2005) and Parker *et al.* (2005). These publications demonstrated that using a forced air source for wind and hose water for rain will elicit and spread Xcc from infected plants. In one experiment in Bock *et al.* (2005), the blower was run for 5 minutes, the same duration as in the 25-m/s artificial wind and rain cull pile experiment, and bacteria were recovered from the water to which the infected plants were exposed. Different experiments in both papers using different durations produced the same results. We would presume that using similar techniques to elicit and spread Xcc from infected fruit would be effective, if fruit was an epidemiologically significant pathway.

The commenter correctly notes that the Gottwald *et al.* (2009) publication did not describe any positive controls for the immunostrips used in the cull pile experiments to determine whether Xcc was present. However, a personal communication with one of the authors of that publication indicates that the experimenters did use positive controls to confirm that the immunostrips were working properly and thus would have indicated that Xcc was present if it had been present.

We disagree with the second commenter that the exposure times in the cull pile experiments in Gottwald *et al.* (2009) were ''short.'' The 5-minute exposure time in the 25-m/s artificial wind and rain experiment was sufficient to infect 1 test plant. The commenter also ignores the field cull pile experiments, which each took place for several weeks, at different times of year.

Finally, it is important to note that our determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc does not rest solely upon the Gottwald *et al.* (2009) cull pile experiments, although they do provide

valuable evidence supporting that determination. Rather, that determination takes into account all the evidence considered in the November 2007 RMA, the updated PRA, and the supplemental RMA, including evidence about the biology of the disease, the effectiveness of disinfectant treatment, the conditions that must be fulfilled for disease transmission to occur, and the fact that the movement of commercial citrus fruit has not been associated with an outbreak of the disease anywhere in the world.

Shiotani et al. (2009)

We also received several comments specifically addressing Shiotani *et al.* (2009).

One commenter stated that, in Shiotani *et al.* (2009), proper positive controls proving that the polymerase chain reaction (PCR) detection technique is working were not included in one set of experiments. (We believe the commenter is referring to the examination of fruit collected from a diseased commercial orchard to investigate the survival of Xcc.)The commenter stated that the lack of controls casts doubts on the results of this research.

The commenter correctly notes that there is no explicit discussion of controls in the ''Materials and Methods'' section of the paper. This does not mean that the proper controls were not used, but we cannot verify that they were. That said, the fact that isolations and bioassays made from the same material also yielded negative results supports the PCR results.

One commenter stated that the Shiotani *et al.* (2009) experiments used a laboratory strain of Xcc that has not been shown to be pathogenic but, the publication stated, ''is believed to be as robust as the wild-type.'' The commenter stated that this demonstrates critical flaws in the experimental design and that the conclusions of Shiotani *et al.* (2009) can thus not be accepted without reasonable doubts.

The commenter quotes from the ''Discussion'' section of the Shiotani *et al.* (2009) publication. In the ''Materials and Methods'' section, the authors discuss the laboratory strain in more detail: ''A marked strain of *X. citri* pv. *citri* (KC21Rif100) that is resistant to rifampicin was used as inoculum. This strain is a stable, spontaneously derived mutant from strain KC21 (Shiotani *et al.*, 2008), which has been shown to be as pathogenic as other strains of *X. citri* pv. *citri* in infection studies.'' We believe this information addresses the commenter's concern.

The Shiotani *et al.* (2009) publication included experiments designed to assess the potential for spread of Xcc from mature Satsuma mandarin fruit inoculated with the marked strain of Xcc mentioned above and suspended in polypropylene net bags in navel orange trees. One commenter noted that, in one of the four experiments conducted, citrus canker was transmitted from culled mandarin fruit to leaves of navel orange trees in an orchard.

Another commenter, responding to the first commenter, noted that the infections in that experiment were not caused by the marked strain of Xcc but by the wild type. Citrus canker is endemic in the area where this study was done, so a tagged strain was used. That way, the commenter stated, the researchers have an idea where the inoculum is coming from. The commenter stated that the fact that wild-type canker bacteria occasionally are caught in traps or cause infection on plants in the experiment does not undermine the conclusion in any way; in fact, it demonstrates that conditions conducive to the transmission of canker existed, and the marked strain on and in fruit did not demonstrate any risks of disease transmission.

We agree with the second commenter.

One commenter stated that the Shiotani *et al.* (2009) publication does not provide a high degree of confidence that transmission of Xcc from contaminated fruit to host plants is not epidemiologically significant. Although no transmission of Xcc was observed, the commenter suggested that it is possible that this was due to unexplained variables. Rainfall data were provided but no information was provided on the growth stage of trap plants, insect presence in the orchard, potential wounds and insect damage, spray history within the orchard, or other significant wind and weather events. Because the experiments were conducted in a commercial orchard, the commenter stated, it would be expected that pest and disease management would have been practiced at some point prior to the study.

As noted earlier, the Shiotani *et al.* (2009) experiments used a marked strain of Xcc because Xcc is endemic in the area where the experiments took place. The wild-type strain of Xcc occurred in the orchard where the experiments took place, throughout the experiments. This indicates that at least some plants in the orchard were at a susceptible growth stage, and in general the transmission of Xcc between trees in the orchard indicates that whatever unexplained variables may have been present did not impede the normal transmission of Xcc.

In Shiotani *et al.* (2009), the authors state, for the initial assay of fruit from diseased orchards, ''No chemicals had been sprayed to control the disease,'' addressing the commenter's concern about the previous employment of disease control methods. Disease control is not addressed directly for the other experiments, including the experiments regarding the potential spread of Xcc from Satsuma mandarin fruits. However, other statements in the publication imply that no disease control techniques were employed in the orchard:

> In September 2006, the Satsuma mandarin orchard in Saga was damaged by typhoon No. 0613. The typhoon brought rain with strong southerly winds with maximum speeds of 50 m/s to the orchard, which is located on a south-facing hillside. The severe meteorological conditions of this typhoon strongly facilitated spread of citrus canker, leading to the highest incidence of the disease in the orchard in the last decade. ... It is most likely that small populations of the wild strain of *X. citri* pv. *citri* survived in the orchard. Citrus canker infection caused by the wild strain indicated that conditions were also conducive for the establishment and spread of the introduced KC21Rif100 strain. The KC21Rif100 strain did not exude from lesions on Satsuma mandarin fruits after they were discarded in an orchard in October 2006, although conditions were conducive for the spread of *X. citri* pv. *citri*.

If disease control techniques had been employed in the orchard, we assume that the authors would not have described the conditions as conducive for the spread of Xcc.

These statements also indicate that information on significant wind and water events was provided, specifically with regard to typhoon No. 0613.

Shiotani *et al.* (2009) did not provide any information on insect presence or pest control in the orchard. The citrus leafminer is known to occur in Japan, but we do not know whether it occurs in the orchard. However, it is important to note that insects themselves are not known to be vectors for Xcc; the presence of the citrus leafminer or another insect in the orchard might increase the severity of canker in the orchard, but it would not enable transmission of Xcc from infected fruit to host plants.

The commenter stated it is likely that naturally infected tissues have a higher

ability to transmit the bacterium than artificially surface-inoculated fruit, which were used in Shiotani *et al.* (2009).

Shiotani *et al.* (2009) determined that the bacteria in the lesions that resulted from the artificial inoculation were viable. We know of no evidence that suggests that bacteria in natural lesions are more effective than surface-inoculated bacteria in spreading Xcc, and the commenter did not supply any.

The commenter stated that another limitation of the design of this experiment is that it did not include a control group to demonstrate tree-to-tree transmission under a similar set of conditions.

Tree-to-tree transmission was demonstrated through the incidence of the wild-type strain of Xcc, which the publication discussed. In this case, the wild-type strain acted as a control to show that transmission of Xcc within the orchard was possible and did occur.

The commenter also stated that the uncertainties cited by the commenter are acknowledged by the authors, who suggested that conditions may have been unfavorable for spread of the bacterium.

The statement in Shiotani *et al.* (2009) that conditions may have been unfavorable for disease spread referred to one replication of the experiment. The publication goes on to note that disease spread occurred at high levels in a subsequent replication:

> In the experiments started in November 2005 and March 2006, no canker symptoms were observed on any branches beneath the discarded fruits. This may be because weather conditions were unfavourable for disease spread during this period. During the experiment started on May 2006, canker lesions were observed on leaves of navel oranges located beneath the discarded Satsuma mandarin fruits. …The severity of the disease was greater in 2006 than in 2005. The incidence of citrus canker in the orchard was 36.2 percent and severity was 18.0. The high incidence may be attributed to typhoon No. 0613 that occurred on September 17, 2006.

In addition, it should be noted that our determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc does not rest solely on the experiments in Shiotani *et al.* (2009), although they do provide valuable evidence supporting that determination. Rather, that determination reflected our analysis of all the evidence considered in the November 2007 RMA, the updated PRA, and the supplemental RMA, as discussed earlier.

Shiotani *et al.* (2009) also examined the survival of Xcc bacteria on the surface of artificially inoculated fruit that were retained for sampling. One commenter noted that viable Xcc was isolated from 3 canker lesions from 2 out of 6 Satsuma mandarin fruit (a cultivar resistant to citrus canker), 3 months after inoculation. Given these results, the commenter concluded that symptomatic citrus fruit (treated or untreated) remain a potential source of inoculum.

We agree with the commenter that some viable bacteria may remain in lesions of infected fruit. However, in those fruits, the strain KC21Rif100 was found in only 3 of 14 lesions andat a bacterial population lower than 3×10^3 cfu per lesion. This is consistent with one of the findings of the November 2007 RMA and the supplemental RMA, which is that the viability of bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested. Diminishing bacterial populations are less likely to provide adequate inoculum to incite infection.

It should also be remembered that the fruit that were sampled and found to have viable bacteria had been stored in protected conditions. The fruit that were artificially inoculated and used in the experiment regarding the potential of spread of citrus canker did not serve as sources of citrus canker transmission, even when the lesions had just been formed and presumably contained high levels of inoculum. The rinds of the artificially inoculated fruits retrieved after 3 days in the orchard did not have any viable bacteria. Finally, as noted earlier in the discussion of Gottwald *et al.* (2009), other evidence indicates that bacteria that remain on the fruit in lesions and wounds after disinfection are not epidemiologically significant.

The commenter is correct to note that Satsuma mandarin is a resistant variety of citrus. As noted in the supplemental RMA, the Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications used citrus cultivars that represented the extremes of susceptibility from highly susceptible (grapefruit) to less susceptible varieties (lemon, mandarins). APHIS assumes cultivars not specifically studied would fall within this range of susceptibility and the results are therefore applicable to all citrus cultivars. In any case, the supplemental RMA and November 2007 RMA consider many different sources of evidence in making the determination that the viability of bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested, not just the Shiotani *et al.* (2009) publication.

One commenter noted that the authors of Shiotani *et al.* (2009) state: ''It is possible that bacterial cells of KC21Rif100 strain could not grow and colonize the surface of the contaminated fruits due to lack of nutrients.'' The commenter stated that, considering that at least a small percentage of fruit is always decaying during shipment and marketing, this decayed fruit can contaminate other fruit with nutrients that will make survival of the bacteria more likely.

The commenter provided no evidence suggesting that this would occur, and we are aware of none. The available evidence suggests that rotting fruit would not provide nutrients that would make survival of Xcc bacteria more likely. For example, Fulton and Bowman (1929) demonstrated that canker does not survive on rotting fruit. In addition, decaying fruit would be decaying due to the presence of other organisms, and Xcc does not compete well with other organisms, as described in Fulton and Bowman (1929) and Leite (1990).

One commenter stated that, at the end of the Shiotani *et al.* (2009) publication, the authors indicate that navel oranges are more susceptible to canker than mandarins. The commenter stated that this indicates that their pathogen survival studies on mandarins will not reflect the true risk of transmission of the pathogen/disease. Two other commenters echoed this concern and stated that, because California's growing situation is quite different than those in the research areas, there are serious issues about the extrapolation of data from study of only a few varieties. Another commenter, approaching this issue differently, suggested that restrictions on the interstate movement of different varieties of citrus fruit could vary based on the variety's resistance to citrus canker.

The Shiotani *et al.* (2009) publication does not actually state that Satsuma mandarins are more resistant to Xcc than navel oranges, although this is widely acknowledged to be true. In any case, as noted earlier, the Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications used citrus cultivars that represented the extremes of susceptibility from highly susceptible (grapefruit) to less susceptible varieties (lemon, mandarins). APHIS assumes cultivars not specifically studied would fall within this range of susceptibility and the results are therefore applicable to all citrus cultivars. The commenters did not provide any specific reasons to question this assumption.

In general, although we recognize that there are limitations in extrapolating from results achieved with Satsuma mandarins, the Shiotani *et al.* (2009) provides valuable evidence supporting our determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc. We took this evidence into account along with the Gottwald *et al.* (2009) publication and the other evidence cited in the November 2007 RMA and the supplemental RMA in making this determination.

Other Issues in the Updated PRA and Supplemental RMA

One of the conclusions in the updated PRA is that standard packinghouse procedures and post-harvest treatments will remove and/or devitalize epiphytic populations of Xcc. This conclusion is echoed in the supplemental RMA.

One commenter stated that the conclusion in the updated PRA that Xcc has a low survival potential is in contrast to earlier research by Golmohammadi *et al.* (2007), who reported that Xcc was frequently detected on fruit with canker-like symptoms in commercial consignments of citrus from Uruguay and Argentina into Spain. These consignments were accompanied by phytosanitary certification stating that fruit had been treated with postharvest bactericides, including chlorine and sodium orthophenylphenate. The presence of Xcc on these samples was confirmed by molecular and pathogenicity testing. Pathogenicity assays on grapefruit leaves confirmed that Xcc cells remained viable and were able to produce symptoms despite the application of postharvest treatments and low temperature storage.

Both the updated PRA and the supplemental RMA addressed Golmohammadi *et al.* (2007). The updated PRA and supplemental RMA state that the results in Golmohammadi *et al.* (2007) indicate that disinfection protocols are not 100 percent effective. Some samples were only positive by PCR protocols. The authors concluded this was probably due to the disinfection treatments, which would reduce bacterial populations, and may induce the noncultivable state in the analyzed lesions. They further suggested that the bacterial cells in the lesions could be stressed after the fruit treatments (washing, disinfection, chemical treatments, transport, and storage at low temperatures for variable periods of time). Pathogenicity tests were successfully conducted only by artificial laboratory inoculations; the epidemiological significance of these results was not evaluated.

Pathogenicity tests of bacteria in the laboratory do not indicate whether the bacteria would actually be able to infect host plants in a field setting, where conditions are likely to be less favorable than in a laboratory. The fact that Golmohammadi *et al.* (2007) concluded that bacterial cells in the lesions could be stressed after the fruit treatments suggests that the bacteria would not have been able to do so, particularly given the results of the experiments Gottwald *et al.* (2009) and Shiotani *et al.* (2009) conducted that addressed the transmission of Xcc from infected fruit to host plants in the field. Since Gottwald *et al.* (2009) and Shiotani *et al.* (2009) both used untreated fruit in their experiments, and Golmohammadi *et al.* (2007) concluded that packinghouse processing and disinfection treatment further reduce the viability of the bacteria, we have determined that the results of Golmohammadi *et al.* (2007) are consistent with the determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc.

One commenter, specifically noting the detections of Xcc on fruit with canker-like symptoms in commercial consignments of citrus from Uruguay and Argentina into Spain, stated that standard harvesting and packinghouse procedures may not effectively eliminate infected fruit from the export pathway.

Both the November 2007 RMA and the supplemental RMA acknowledge this. However, these procedures do reduce the prevalence of viable Xcc in commercial consignments of fruit, thus bolstering the conclusion that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc.

One commenter stated that the supplemental RMA claims that the ''uncertainties'' recognized in the November 2007 RMA are now answered, but the question of additional ''uncertainties'' is completely disregarded.

The supplemental RMA has an extensive discussion of remaining uncertainties in the discussion of options at the end of the document. The commenter did not identify any specific uncertainties that the supplemental RMA did not address.

One commenter stated that, in the supplemental RMA, there is not a single biological reference to fruit pests such as the peel miner and to the fact that there is no scientific work/information for its impact on diseases such as citrus canker. The supplemental RMAsimply disregards this classic epidemiological factor under the general assumption ''Vectors do not have a role in disease epidemiology and if they do, it is not subject to regulation.'' The commenter stated that this disregard of valid, researchable questions is highly disturbing.

The role of insects in citrus canker outbreaks was discussed in the November 2007 RMA. The supplemental RMA does not recreate or revise the entire body of evidence cited in the November 2007 RMA, but rather builds on that body of evidence and evaluates those areas of evidence addressed by the new research. Because none of the newer research cited in the supplemental RMA addressed the role of insects in citrus canker outbreaks, we did not update the discussion in the November 2007 RMA.

With regard to the issue of vectors, one commenter stated that canker is a local lesion disease that does not invade the vascular system and is not transmitted by sucking insects or mites, including citrus leafminer and peel miner. The commenter stated that citrus leafminer is not a vector for the canker bacterium.

The November 2007 RMA indicates that 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 known to be a vector for the spread of citrus canker. In the November 2007 final rule, we discussed the peel miner, stating that 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, however, 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.

We also note that there exists no evidence indicating that the peel miner is a vector for citrus canker, and we would presume that the peel miner is not a vector, for the reasons cited by the second commenter.

Comments on the November 2007 RMA

The November 2007 RMA contained a discussion of the potential for introduction and establishment of Xcc in various climatic conditions.

One commenter stated that the idea that California has unfavorable environmental conditions for pathogen

establishment is simply untrue. The commenter stated that summer monsoons commonly go through the Imperial Valley, and thunderstorms with high winds occasionally occur in the Central Valley (both important citrus-producing areas of California), while humidity can reach adequate levels for canker establishment in the coastal areas of Ventura County (lemon-producing areas).

The November 2007 RMA states: ''Using hourly wind speed and precipitation, monthly average temperature, and annual and seasonal precipitation data to determine the expected incidence and severity of citrus canker if introduced into California, Borchert *et al.* (2007) concluded that favorable events in California citrus growing areas occurred '… predominantly during the winter season when precipitation is greatest, but temperatures are less conducive for infection activity and citrus growth. This would likely result in low incidence and severity of citrus canker in California if the disease were introduced…' …The 'Mediterranean' climate (dry summers) typical of most of California and the arid climate of Arizona make [Xcc] establishment less likely in those States. However, in microclimates with highly susceptible cultivars such as along the California coast between San Diego and Ventura establishment is still possible, as demonstrated by the occurrence of citrus canker disease in Iran and the Arabian Peninsula on a highly susceptible variety of Mexican lime.''

We acknowledge that, as the commenter stated, summer monsoons and thunderstorms occur in California, but that is not inconsistent with the discussion in the November 2007 RMA. The information presented by the commenter has not led us to change the conclusions in the November 2007 RMA regarding the suitability of California's climate for the establishment of citrus canker.

One commenter stated that we should have more solid information on the source of previous outbreaks before making the changes we proposed.

The November 2007 RMA also analyzed the information available on the source of previous outbreaks. It concluded, ''In summary, there is an unfortunate lack of conclusive information regarding the origins of previous outbreaks. Most published accounts are speculative. However, whatever the lack of certainty may be regarding the theories of [Xcc] introduction pathways, they all agree that trees or propagative tree parts are most likely the original source of [Xcc] introduction. Conclusive evidence that fresh fruit is a pathway for the introduction of [Xcc] has never been presented.'' The November 2007 RMA also noted, and the supplemental RMA repeated, that ''no canker outbreaks have ever been associated with the entry of fruit into the United States or anywhere in the world, nor has the ability of fruit to serve as a pathway of [Xcc] dissemination ever been demonstrated in any scientific experiment, and it seems very unlikely that fruit would be an epidemiologically significant pathway.''

The evidence that has been developed and presented in the two studies that prompted the preparation of the updated PRA and supplemental RMA is consistent with the historical record on the source of citrus canker outbreaks, which largely ties them to the movement of infected nursery stock rather than the movement of infected fruit.

Compliance Agreements and Leaves

In addition to the requirement for treatment with an APHIS-approved disinfectant, we proposed to retain the requirement that regulated fruit moved interstate from an area quarantined for citrus canker be free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit. We proposed to retain this requirement because other plant parts pose different risks than fruit does; canker lesions on leaves, for example, typically have much higher bacterial populations than canker lesions on fruit.

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

Two commenters stated that eliminating mandatory inspection of fruit to be moved interstate for visible symptoms of citrus canker raises questions about how APHIS will assure adherence to compliance agreement requirements.

As stated, we will continue to inspect commercial packinghouses that pack fruit to be moved interstate to verify that they are adhering to the requirements in the regulations, as agreed to in the compliance agreement. These inspections will be conducted regularly. Inspectors will check treatments to ensure that they are being performed in accordance with the regulations (for example, verifying the pH level and the concentration in a sodium hypochlorite treatment). Inspectors will also open and inspect a random sample of packed boxes of fruit to verify that the packed fruit is free of leaves, twigs, and other plant parts. We have experience successfully enforcing compliance agreements with similar requirements for many other domestic quarantine programs.

One commenter stated that inadvertent citrus leaves included in packed boxes of fruit may also carry the pathogen/disease from one location to another.

Another commenter stated that, in the very unlikely event that a lesioned leaf would be present in a fruit load, conclusions that fruit is not an epidemiologically significant pathway can confidently be extended to aging and drying leaves. The commenter stated that it is unlikely that this source of inoculum would represent any different risk than fruit for inoculum production and disease transmission.

Although the second commenter may be correct, we have not undertaken a thorough assessment of the risks associated with allowing the interstate movement of leaves of regulated species from a quarantined area. We would need to do so before allowing the interstate movement of leaves. Therefore, we proposed to retain the requirement discussed earlier.

The first commenter is correct that leaves could inadvertently be moved in boxes of packed fruit. However, the requirement that fruit be free of leaves serves to mitigate that risk, as packinghouse employees will need to check to make sure that leaves are not inadvertently packed so that the packinghouse will be able to pass inspections conducted under the compliance agreements and continue to pack fruit for interstate movement. In addition, leaves are commonly removed from boxes of packed citrus fruit as part of commercial production practices. Given these conditions, we have determined that it is not necessary to provide for any further restrictions on the interstate movement of fruit in order to prevent the inadvertent interstate movement of leaves.

Citrus Greening

One commenter stated that we should consider ongoing research on evaluating citrus fruit as a potential source for the

Asian citrus psyllid (ACP), the vector of citrus greening, to acquire 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 last updated on September 21, 2009. The September 21, 2009, Federal Order does not restrict the interstate movement of fruit from an area quarantined for ACP, except to require that the fruit be cleaned using normal packinghouse procedures. These procedures are sufficient to remove ACP. Fruit itself has not been shown to be a potential pathway for the spread of citrus greening.

The commenter did not cite any specific research that is ongoing regarding ACP's ability to acquire citrus greening directly from fruit, and we are not aware of any. However, if we determine that additional restrictions need to be placed on the interstate movement of fruit from areas quarantined for ACP, we would include those restrictions in a new Federal Order or in separate citrus greening regulations, not in the citrus canker regulations.

Illegal Movement of Nursery Stock

Section 301.75-6 of the regulations prohibits, with limited exceptions, the interstate movement of citrus nursery stock from an area quarantined for citrus canker. Three commenters stated that the potential illegal movement of nursery stock was the most risky pathway for the introduction of citrus canker into commercial citrus-producing States other than Florida. One recommended that, given the limited resources available to plant health regulatory programs, resources should be concentrated on this pathway. This commenter requested additional resources to deal with the pathway.

One stated that adoption of the proposed rule would likely increase the illegal movement of Florida citrus nursery plants into Texas, simply because the general public may conclude it is safe to transport citrus nursery plants as well.

Two of the commenters stated that efforts should be undertaken to increase public awareness of the prohibition against moving nursery stock interstate from citrus canker quarantined areas. Both of these commenters also requested that enforcement efforts against this illegal movement continue; one requested increased resources for those efforts.

We agree with these commenters that the illegal movement of nursery stock is a high-risk pathway. We have several efforts underway to prevent the spread of citrus canker and citrus greening through the illegal movement of nursery stock. In fiscal year 2009, we conducted enforcement activities that included:

- Monitoring of retail markets and wholesale distributors in commercial citrus-producing States;
- Monitoring the Internet for the sale and distribution of citrus plants from quarantined areas;
- Monitoring retail and wholesale establishments in States other than commercial citrus-producing States for citrus plants and plant products from quarantined areas; and
- Conducting operations in concert with State officials at State checkpoints to ensure that shipments moving out of Florida do not contain plants or plant products whose movement is prohibited and that shipments entering commercial citrus-producing States do not contain such products.

We are also sampling nursery stock that is found moving illegally to determine whether it is infected with a citrus disease. In all these activities, we work with State and local agencies, and we notify them of whatever violations we discover.

We are also conducting extensive outreach efforts regarding the movement of nursery stock from quarantined areas. The Web site (*http://www.saveourcitrus.org*) provides a public clearinghouse of information on safeguarding U.S. citrus resources and preventing the illegal movement of citrus plants from quarantined areas. We will continue to employ resources on enforcement and outreach as necessary and as budget constraints allow.

We disagree with the commenter who stated that the proposed rule would likely increase introduction of illegal Florida citrus nursery plants into Texas. Although regulated fruit has been allowed under the regulations to move interstate to States other than commercial citrus-producing States, regulated nursery stock, except kumquat plants produced under conditions designed to prevent their infection with citrus canker, is not allowed to move interstate. Thus, the difference between the allowable movement of regulated fruit and regulated nursery stock already exists, and our enforcement and outreach efforts take it into account.

International Trade

Two commenters expressed concern regarding trade issues. Both expressed concern that the rule might result in trading partners imposing additional restrictions on the export of citrus fruit from the United States. One stated that we should not finalize the proposed rule until we know that the European Union (EU) agrees with the science that serves as a basis for the rule, citing fears of trade interruptions.

Another stated that the objective of the rule was to demonstrate to our trading partners that there is no risk of spread of citrus canker via fruit, thus allowing Florida to export fresh fruit to countries that currently restrict or prohibit such importations. This commenter stated that jeopardizing citrus-producing areas in the United States so that Florida can trade with citrus-producing areas around the world is unacceptable.

Regulated fruit from Florida is currently exported to other countries, including the EU, in accordance with those countries' regulatory requirements. We proposed to relieve restrictions on the interstate movement of fruit from an area quarantined for citrus canker based on our determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of citrus canker, not as part of an attempt to reduce or remove restrictions on the exportation of Florida citrus fruit to other countries. Other countries are not obligated to change their requirements for the importation of plant products based on changes in our regulations on the interstate movement of plant products.

We are willing to have exchanges with foreign national plant protection organizations to discuss our findings, but because we have determined the restrictions that have been in place on the movement of fruit from a quarantined area are no longer justified by the scientific evidence, we are removing restrictions that are no longer warranted.

Kumquats

One commenter requested that we remove kumquats from the list of regulated articles in § 301.75-3(a), thus allowing kumquat fruits to be moved interstate from the quarantined area with leaves and stems, as they are commonly marketed. The commenter stated that there has not been any citrus canker found in Pasco County, FL, where all of the commenter's kumquats are grown, and that there has been no citrus canker found in commercial kumquat groves. The commenter also stated that a professor at the University of Florida's horticulture department has stated that ''Nagami kumquats and citrus canker are incompatible...Far

from acting as a host, the Nagami kumquats suppress it by causing the inoculated tissue to die and the affected leaves to fall off.''

Although there are numerous references stating that kumquats are highly resistant to citrus canker (see Gottwald *et al.* (2002) and Francis *et al.* (2009)), we are aware of no references that state that citrus canker does not infect kumquats, or that kumquats are incompatible with citrus canker. For that reason, we list kumquat plants and plant parts (including fruit, leaves, and stems) as regulated articles in § 301.75-3(a). If evidence is developed that indicates that citrus canker does not infect kumquats, we will amend the list of regulated articles accordingly.

With respect to the commenter's specific concern, we note that if kumquats were removed from the list of articles regulated for citrus canker, kumquat leaves would still be prohibited from moving interstate from Florida under the September 21, 2009, Federal order on citrus greening, which prohibits the interstate movement of plants and plant parts other than fruit from species that are hosts of citrus greening.

Regulatory Impact Analysis

Addressing the preliminary regulatory impact analysis and initial regulatory flexibility analysis we prepared for the proposed rule, two commenters stated that the document devotes almost 18 pages to the expected impacts of the proposed rule on the Florida industry. In the 2½ pages addressing the expected effects for the other commercial citrus-producing States, it is noted that APHIS expects ''the primary effect of the rule would be to preserve Florida's fresh market in the long run.'' The commenters noted that the analysis states that ''...a reduction in the packout rate for fresh market fruit in the other commercial citrus-producing States due to citrus canker infestation would likely have a larger economic impact than has been experienced by Florida, due to their greater reliance on fresh citrus sales, especially of oranges.'' The analysis also states that ''in the event that citrus canker were to spread to other commercial citrus-producing States, we do not anticipate that other commercial citrus-producing States would find profitable alternative markets for fruit that could not be sold on the fresh market.'' The commenters stated that this rule change is clearly for the benefit of the Florida citrus industry, and the interstate movement of citrus fruit from areas quarantined for citrus canker into commercial citrus-producing States should not be allowed as the risks to the citrus industry in other commercial citrus-producing States are too high.

As discussed in the updated PRA and supplemental RMA, commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc. We prohibit the interstate movement from a quarantined area of plants and plant products that are more likely pathways, such as grass clippings, plant clippings, tree clippings, and nursery stock, which (as other commenters noted) is the highest-risk pathway for the spread of citrus canker.

We acknowledge that citrus produced in other commercial citrus-producing States is produced primarily for the fresh market; for that reason, protecting the appearance of the fruit is critical for citrus production in for those States. We are committed to protecting against the spread of citrus canker to other commercial citrus-producing States, as evidenced by the mitigations required by the final rule for the interstate movement of fresh fruit from quarantined areas and the other movement restrictions in the regulations.

Consistent with the requirements of the Regulatory Flexibility Act (RFA), our preliminary regulatory impact analysis and initial regulatory flexibility analysis focused on any significant impacts the proposed rule could have on small entities. We determined that significant impacts on small entities, if they occur as a result of this final rule, are most likely to be experienced in Florida; the economic effects of allowing freer movement of Florida citrus are likely to be distributed among consumers in other States, as discussed.

Miscellaneous Change

We proposed to revise the definition of *commercial packinghouse* in § 301.75-1 to read: ''An establishment in which space and equipment are maintained for the primary purpose of disinfecting and packing citrus fruit for commercial sale. A commercial packinghouse must also be licensed, registered, or certified with the State in which it operates and meet all the requirements for the license, registration, or certification that it holds.''

In this final rule, we are changing the proposed definition to indicate specifically in the second sentence that the commercial packinghouse must be licensed, registered, or certified for handling citrus fruit. The proposed definition could have been interpreted as referring to any type of license, registration, or certification; indicating that the license, registration, or certification of a commercial packinghouse must be specifically for handling citrus fruit provides additional specificity and clarifies the intent of the definition.

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

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infected Satsuma mandarin fruit. *Crop Protection* 28:19-23.

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

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Order 12866, and an analysis of the potential economic effects of this action on small entities, as required by the RFA. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

APHIS has determined that this final rule will continue to prevent the spread of citrus canker from quarantined areas while allowing the interstate movement of fruit and lessening the compliance burden associated with the fruit movement regulations. The rule will remove the risk of lot rejection of fresh fruit intended for interstate shipment solely because the fruit exhibits citrus canker symptoms, thereby supporting the long-term preservation of domestic fresh fruit markets for Florida's commercial packinghouses and growers. Fresh citrus fruit will no longer require diversion to other uses or markets because of citrus canker symptoms. In addition, APHIS is removing the current prohibition on the movement of Florida's fresh citrus fruit to other commercial citrus-producing States. We do not anticipate that citrus production in these States will be significantly affected by Florida's market reentry.

While the lots rejected during the 2008-09 season were successfully diverted for processing or to fresh fruit markets within Florida or outside the United States, affected citrus producers and commercial packinghouses incurred revenue declines because of elimination charges and the lower prices received due to product diversion. The cost of producing citrus fruit intended for the fresh market is greater than the cost of production for the processed market, where the physical appearance of the fruit is not important.

Impact on Small Entities

The RFA requires that agencies consider the economic impact of rule changes on small businesses, organizations, and governmental jurisdictions. Section 605 of the RFA allows an agency to certify a rule if the proposed rulemaking will not have a significant economic impact on a substantial number of small entities. Following is the factual basis for such certification in this case.

Based on the determination that fresh citrus fruit treated using an APHIS-approved disinfectant is not an epidemiologically significant pathway for transmission of the disease, this final rule will remove the requirement of an APHIS inspection of fresh packed citrus intended for the domestic market for symptoms of citrus canker disease. The final rule will require the treatment of fresh citrus from a commercial packinghouse with an APHIS-approved disinfectant. The final rule will relieve prohibitions associated with the current limited permit requirement, and allow the reentry of fresh citrus fruit from Florida into other commercial citrus-producing States. This action is being taken to relieve restrictions on the Florida citrus industry that we believe are no longer warranted while continuing to prevent the spread of citrus canker to other commercial citrus-producing States and territories.

Florida's citrus commercial packinghouses and fresh citrus producers comprise the industries that will be directly affected by this final rule. The small business size standard for citrus fruit packing, as identified by the Small Business Administration (SBA) based upon the North American Industry Classification System (NAICS) code 115114 (Postharvest Crop Activities) is $6.5 million or less in annual receipts. There are currently 174 commercial packinghouses in Florida under APHIS Packinghouse Compliance Agreements, 56 of which are registered with the Florida Department of Agriculture and Consumer Services' Division of Fruit and Vegetables. While the classification of all of these establishments by sales volume is not available, it is estimated that approximately 40 of the 56 registered commercial packinghouses are the top-grossing citrus commercial packinghouses. The remaining packinghouses are small establishments known primarily as gift packers. At least 95 percent of Florida fresh citrus shipments are packed by the top 40 (23 percent) commercial packinghouses in the State.[4] The Fresh Shippers Report, as reported by the Citrus Administrative Committee, details quantities of fresh citrus shipped by the top 40 shippers each season.[5] During the 2007-08 season, annual sales for 14 of the top 40 shippers (35 percent) were below the SBA size standard of $6.5 million. It is estimated that at least 82 percent of Florida's citrus packers, including the small gift packers, will be considered small according to the SBA size standards.

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

A majority of the Florida citrus producers that will be affected by the final rule are small, based on 2007 Census of Agriculture data and SBA guidelines for entities classified within the farm categories Orange Groves (NAICS 111310) and Citrus (except Orange) Groves (NAICS 111320). SBA classifies producers in these categories with total annual sales of not more than $750,000 as small entities. According to 2007 Census data, there were a total of 6,061 citrus farms in Florida in 2007. Of this number, 90 percent had annual sales in 2007 of less than $500,000, which is well below the SBA's small-entity threshold of $750,000.[6] Any costs associated with the final rule are expected to be minimal, especially given the producers' gains from fewer

[4] ''Fresh Shippers Report: 2007-08 Season Through July 31, 2008,'' Citrus Administrative Committee, August 8, 2008. (*http://www.citrusadministrativecommittee.org/*)

[5] Ibid.

[6] Source: SBA and *2007 Census of Agriculture*.

rejections of fresh citrus lots destined for the domestic market.

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

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

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.

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.[7] 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

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

List of Subjects in 7 CFR Part 301

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

■ Accordingly, we are amending 7 CFR part 301 as follows:

PART 301–DOMESTIC QUARANTINE NOTICES

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75-15 issued under Sec. 204, Title II, Public Law 106-113, 113 Stat. 1501A-293; sections 301.75-15 and 301.75-16 issued under Sec. 203, Title II, Public Law 106-224, 114 Stat. 400 (7 U.S.C. 1421 note).

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

§ 301.75-1 Definitions.

* * * * *

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

* * * * *

§ 301.75-4 [Amended]

■ 3. Section 301.75-4 is amended as follows:

■ a. In paragraph (d)(2)(ii)(D), by removing the first sentence.

■ b. By removing paragraph (d)(6).

■ 4. Section 301.75-7 is revised to read as follows:

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

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

(1) The regulated fruit was packed in a commercial packinghouse whose owner or operator has entered into a compliance agreement with APHIS in accordance with § 301.75-13.

(2) The regulated fruit was treated in accordance with § 301.75-11(a).

(3) The regulated fruit is free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit.

(4) If the fruit is repackaged after being packed in a commercial packinghouse and before it is moved interstate from the quarantined area, the person that repackages the fruit must enter into a compliance agreement with APHIS in accordance with § 301.75-13 and issue and attach a certificate for the interstate movement of the fruit in accordance with § 301.75-12.

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

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

[7] Go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0023*). The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

Done in Washington, DC, this 15th day of October 2009.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9–25328 Filed 10–21–09: 8:45 am]

BILLING CODE 3410–34–S

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2008–BT–TP–0007]

RIN 1904–AB77

Energy Conservation Program: Test Procedures for Fluorescent Lamp Ballasts (Standby Mode)

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE) is amending its test procedures for fluorescent lamp ballasts under the Energy Policy and Conservation Act. These amendments address the measurement of energy consumption of fluorescent lamp ballasts in the standby mode. These amendments do not address energy consumption in off mode, because DOE has determined that these products do not operate in off mode.

DATES: This rule is effective November 23, 2009. The incorporation by reference of certain publications listed in this rule was approved by the Director of the Federal Register on November 23, 2009.

ADDRESSES: You may review copies of all materials related to this rulemaking at the U.S. Department of Energy, Resource Room of the Building Technologies Program, 950 L'Enfant Plaza, SW., Suite 600, Washington, DC, (202) 586–2945, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Please call Ms. Brenda Edwards at the above telephone number for additional information regarding visiting the Resource Room.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Graves, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Telephone: (202) 586–1851. E-mail: *Linda.Graves@ee.doe.gov.*

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC–72, 1000 Independence Avenue, SW., Washington, DC 20585. Telephone: (202) 586–5827. E-mail: *Eric.Stas@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: This final rule incorporates by reference into Appendix Q of Subpart B of Title 10, Code of Federal Regulations, part 430, the following industry standards from the American National Standards Institute (ANSI):

1. ANSI Standard C82.2–1984, Revision of ANSI C82.2–1977 ''American National Standard for Lamp Ballasts—Methods of Measurement,'' October 21, 1983; and

2. ANSI Standard C82.2–2002, Revision of ANSI C82.2–1994 (R1995) ''American National Standard for Lamp Ballasts—Methods of Measurement of Fluorescent Lamp Ballasts,'' June 6, 2002.

Copies of the ANSI standards can be obtained from the American National Standards Institute, 25 W. 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900, or *http://www.ansi.org.* One can also view a copy of these standards at the U.S. Department of Energy, Resource Room of the Building Technologies Program, 950 L'Enfant Plaza, SW., 6th Floor, Washington, DC 20024, (202) 586–2945, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

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I. Authority and Background

Title III of the Energy Policy and Conservation Act (42 U.S.C. 6291 *et seq.*; EPCA or the Act) sets forth a variety of provisions designed to improve energy efficiency. Part A [1] of Title III (42 U.S.C. 6291–6309) establishes the ''Energy Conservation Program for Consumer Products Other Than Automobiles,'' which covers consumer products (all of which are referred to below as ''covered products''), including fluorescent lamp ballasts (ballasts). (42 U.S.C. 6291(1)–(2) and 6292(a)(13))

The program consists essentially of testing, labeling, and Federal energy conservation standards. The testing requirements consist of test procedures that manufacturers of covered products must use as the basis for certifying to DOE that their products comply with EPCA energy conservation standards and for representing the energy efficiency of their products.

Section 323(b) of EPCA (42 U.S.C. 6293 (b)) authorizes DOE to amend or establish new test procedures as appropriate for each covered product. It states that ''[a]ny test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use, * * * or estimated annual operating cost of a covered product during a representative average use cycle or period of use, as determined by the Secretary [of Energy], and shall not be unduly burdensome to conduct.'' (42 U.S.C. 6293(b)(3)) In addition, EPCA states that DOE ''shall determine, in the rulemaking carried out with respect to prescribing such procedure, to what extent, if any, the proposed test procedure would alter the measured energy efficiency * * * of any covered product as determined under the existing test procedure.'' (42 U.S.C. 6293(e)(1)) If DOE determines that the amended test procedure would alter the measured efficiency of a covered product, DOE must amend the applicable energy conservation standard accordingly. (42 U.S.C. 6293(e)(2))

For ballasts, the test procedures must be ''in accord with ANSI Standard C82.2–1984 or other test procedures determined appropriate by the Secretary.'' (42 U.S.C. 6293(b)(5)) DOE's existing test procedures for ballasts, adopted pursuant to the above provisions, appear at Title 10 of the Code of Federal Regulations (CFR) part 430, subpart B, appendix Q (''Uniform

[1] For editorial reasons, Part B (Consumer Products) and Part C (Commercial Equipment) of Title III of EPCA were redesignated as Parts A and A–1, respectively, in the United States Code.